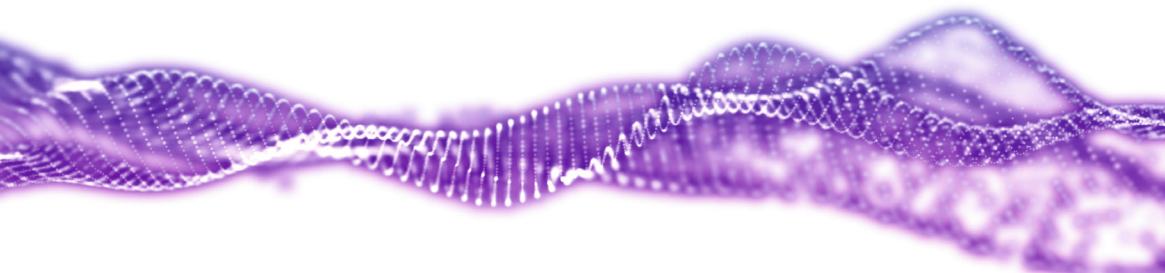
elderbrook
linking minds

Our Products and Services

Linking Minds to Find Tomorrows Solutions Today.



We are commited to the concept of “linking minds”

Dear colleagues,

At elderbrook solutions GmbH, we understand that the journey of clinical development requires more than just service providers – it demands true partners with proven expertise.

Our commitment to excellence has positioned us as valuable consultants in an increasingly complex pharmaceutical landscape. We take pride in our high-quality standards that have become synonymous with the elderbrook name across the industry.

Our clients value that we not only deliver high quality, but also take full ownership of both the quality and the outcome of every project. We see things through to completion and make sure that every detail is taken care of.

Our success is driven by our team's extensive knowledge, with many members recognized as world-class leaders in their areas of expertise.

When you choose elderbrook, you are selecting a partner that values your success as much as their own reputation for excellence.

Best regards,

Dr. Markus Pietsch
Vice President

Our expertise portfolio

Clinical Data Management

We ensure data integrity across clinical trials using advanced technologies and systems like Veeva, RAVE, and Oracle Clinical. Our team handles everything from protocol input to database lock, supporting 150+ trials across all therapeutic areas.

Statistical Programming

With 100+ global programmers, we deliver fast and agile support using SAS, R, and Python. Provision of SDTM/ADaM datasets and associated tables, figures and listings (TLFs), regulatory submissions, safety monitoring, and advanced data visualizations to transform clinical trial data into actionable insights.

Biostatistics

Our biostatisticians design and execute robust statistical methodologies for clinical trials. From study design and sample size calculation to adaptive designs and regulatory submissions, we deliver precise data analysis across all clinical phases.

EU HTA Regulatory Support

Our HTA experts navigate the new EU Health Technology Assessment Regulation, specializing in Joint Clinical Assessments (JCAs) for cancer medicines and ATMPs. We provide strategic planning, dossier development, and market access optimization to bridge regulatory requirements and commercial success.

"Having supported more than 250 clinical trials via elder brook, we leverage our expertise to secure high-quality-drug approvals, driven by our unwavering commitment to patients."

James Lee
Head of Biostatistics & Clinical Data Sciences

Clinical Software Development

We digitalize your processes with tailored software solutions—covering every phase from concept to implementation. Our in-house team delivers high-quality, GxP-compliant applications using agile methodologies, ensuring rapid delivery, robust testing, and full transparency for your digital transformation.

Project Management

Our Project Management team combines PRINCE2 and Agile methodologies with expert risk management to deliver seamless project execution on time, within budget, and with uncompromising quality standards.

Computerized System Validation

Validation can be complex - let us handle it for you. Our CSV experts ensure your clinical systems meet the highest standards of compliance and data integrity. With our "Quality as a Service" approach, we simplify validation so you can focus on your core objectives.

IT-Application Management

We deliver end-to-end IT application management tailored to the pharmaceutical industry, overseeing every phase from concept and procurement through deployment, daily operations, and secure retirement, all within a GxP-compliant framework. Our experts optimize and integrate your systems, provide ongoing support, user training, and quality assurance, and serve as a single point of contact - ensuring transparent, efficient processes and empowering your team to focus on core business objectives.

Archiving

We provide comprehensive GxP-compliant archiving solutions for secure, long-term preservation of clinical trial documents and data across all regulated domains - GMP, GLP, GCP, and pharmacovigilance. Our expert team manages everything from archive planning and development to data migration, ensuring full regulatory compliance with ICH Guidelines, ISO standards, and 21 CFR Part 11 requirements while maintaining complete data integrity and traceability throughout retention periods.

Clinical Data Management

Empowering Precision with Data-Driven Insights

At the forefront of our pharmaceutical innovations, the Data Management Department plays a critical role in ensuring the integrity, accuracy, and accessibility of clinical data.
Our team of dedicated professionals is responsible for the collection, organization, and maintenance of high-quality data throughout the lifecycle of clinical trials.

We leverage advanced data management technologies and industry best practices with experience of over 250 trials to streamline processes, reduce redundancy, and ensure compliance with regulatory standards. By transforming raw data into actionable insights, we support researchers, statisticians, and decision-makers in delivering safe, effective treatments to patients worldwide.

Our commitment to excellence in data management ensures that every piece of information is handled with precision and care, contributing to the success of our clinical programs and the advancement of medical science.

- Experienced, Lead Data Managers/Engineers
- 100% of our experienced and expert Data Managers are fully trained within Veeva CDMS/CDB, RAVE, Oracle Clinical, JReview, JUMP
- From Protocol input to Database Lock and everything in between (eCRF specification, testing, production, edit checks, DTAs, cleaning, listings, reconciliations, aCRF, SDRG etc.)
- All Therapeutic Areas with experts in Oncology, Diabetes, Hypertension (Metabolism), COPD (Respiratory), CREA
- SDTM Experts including mapping and transformation/define.xml
- Pinnacle 21 Enterprise (P21E)
- QC of submission packages
- SAS experience

Alison Monckton
Global Head of Data Management

Statistical Programming

Turning Data into Insight by coding with precision and delivering with confidence

Statistical programmers provide the insights that help plan and design clinical trials, ensure conduct runs smoothly and report and package the findings for all types of publication and submission documents.

We have over 100 statistical programmers across the globe to provide a fast and agile supporting network and can provide teams in all time zones to support and work alongside your business needs.

- Broad background in all statistical programming languages, with a high focus on SAS, R and Python.
- Production of safety and efficacy analyses for regulatory submissions and publications
- Creation and validation of SDTM and ADaM
- Creation and validation of TLFs
- Submission Support (BIMO , CLINSITE and Post Submission Support)
- In house macros/tools development
- Standards Library creation and maintenance
- Safety monitoring, interim analysis and reporting
- Exploratory and meta-analysis
- Support Quality Monitoring, Data Monitoring and Scientific Steering Committees
- Data Visualization and R-Shiny applications / tools
- HTA Dossier

"Our global team is dedicated to transforming raw data into actionable insights, ensuring your clinical trials are supported short term with precision and expertise."

William Quick
Global Head of Statistical Programming

Biostatistics

Statistical Excellence Driving Innovation

Our team of skilled biostatisticians collaborates closely with clinical researchers to develop and apply robust statistical methodologies that drive meaningful insights and support the advancement of medical knowledge.

We are committed to delivering precise, reliable, and interpretable data that underpin regulatory submissions, guide clinical development, and ultimately improve patient outcomes. By leveraging advanced statistical techniques and industry best practices, we contribute to the success of our clinical programs and help shape the future of health-care.

- Leading all statistical activities in the preparation, conduct and analysis of Phase I to Phase IV studies
- Sample size calculation using different tools (including EAST, nQuery and R)
- Study simulations to evaluate operating characteristics of study designs for the planning of new studies
- Statistical input of Clinical Trial Protocol (CTP)
- Choice of endpoints
- Expert knowledge on Estimands and their implementation
- Creation of Statistical Analysis Plan (SAP) and TLF shells
- Handling of missing data, including, for example, multiple imputation and tipping point analysis
- Adaptive designs
- Experience in SAS and R
- Bayesian analysis
  Creation of statistical sections of the clinical trial reports
- Results disclosure for ct.gov
- Create and contribute to articles and posters
  Training on statistical topics for statisticians and non-statisticians
- Consultancy and authoring of templates and standard operating procedures for clients
- Participation in safety reviews as independent statistician
  Experience in NDA submission related work (FDA, EMA, PMDA, NMPA and others), including Advisory committees

EU HTA Regulatory Support

Proactive Solutions for EU HTA Readiness

We provide specialized support for pharmaceutical and biotech companies navigating the new EU Health Technology Assessment Regulation implemented in January 2025. This landmark legislation introduces mandatory Joint Clinical Assessments (JCAs) for new cancer medicines and Advanced Therapy Medicinal Products.

Our team of HTA specialists helps transform these regulatory requirements into strategic advantages, accelerating patient access to innovative oncology treatments while optimizing value demonstration across European markets.

Our Specialized Services:

- Strategic planning for EU HTA compliance throughout development
- Development of submission-ready JCA dossiers
- PICO framework analysis across EU member states
- Comparative effectiveness evidence generation
- Post-Licensing Evidence Generation (PLEG) design
- Timeline synchronization between EMA and HTA submissions
- Market access optimization leveraging JCA outcomes
- Expert navigation of the secure HTA IT Platform

With deep understanding of both the centralized JCA process and national pricing variations, our HTA experts position your oncology innovations for success in this new regulatory landscape. We blend regulatory expertise with market access strategy to help clients demonstrate value under the EU HTA framework, potentially accelerating time to market while optimizing pricing and reimbursement outcomes.

"Success in the new EU HTA landscape hinges on aligning regulatory and HTA strategies early."

Michaela Kohring
Vice President

Clinical Software Development

Digital Solutions for Modern Healthcare Challenges

We digitalize your processes - empowering you to master digital transformation with high-quality software tailored precisely to your needs. From your initial idea to a fully operational solution, our in-house team guides you through every phase of modern software development:

- Design Thinking: Creative ideation and innovative solution concepts
- Requirements Engineering: Precise definition of your needs
- UI/UX Design: User-centric interfaces for intuitive experiences
- Prototyping: Early models for rapid feedback
- Implementation: Robust, scalable software development
- Release: Seamless deployment
- Support & Maintenance: Ongoing care for lasting performance

Quality is our standard, not an option. Whether your project requires GxP compliance or not, our software is always crafted using state-of-the-art coding guidelines, thoroughly tested with automated tools, and delivered with comprehensive, responsible documentation.

We believe in constant learning, rapid feedback cycles, short time-to-market, and full transparency - embracing agile methodologies for continuous improvement. For smaller or straightforward projects, we are equally experienced in delivering results within classical project environments.

"With us, your digital tools are not just tools; they are strategic assets."

Dr. Max Horneck
CEO

Project Management

Navigating Complexity with Proven Methodologies

elderbrook's project management team combines PRINCE2 and Agile methodologies to deliver high-quality results on time and within budget.

- Project Management at elderbrook ensures the success of both internal and external projects through meticulous planning and execution.

- Utilizing a blend of PRINCE2 and Agile methodologies, our team brings a wealth of industry knowledge and expertise to every project.
  Our Project Management team is dedicated to delivering high quality results, managing risks effectively and meeting client expectations, guaranteeing projects are delivered on time and within budget.

- We leverage innovative systems and tools to streamline processes and enhance efficiency, driving forward our success in clinical projects and fostering innovation and excellence within the industry.

- With many years of experience in the operational areas of the pharmaceutical, insurance, finance and IT industries, we enrich project management with appropriate expertise.

"We bring innovation to project management, ensuring your projects are executed with excellence."

Gernot Menzer
Head of Project Management

Computerized System Validation

Your Assurance for Audit-Ready Solutions

Reliable, compliant, and audit-ready—our CSV services are built to safeguard your critical systems. We streamline validation processes while adapting to your unique operational needs. From initial planning to final reporting, our team is dedicated to delivering quality.

- End-to-End Validation Expertise: Our team delivers full-cycle CSV solutions, from requirements specification to final reporting, ensuring regulatory compliance and data integrity across all clinical systems.
- Built on Proven Internal Standards: We apply the same rigorous validation methodologies used for our own GxP-compliant systems, guaranteeing industry-best practices for your critical infrastructure.
- Quality as a Service Implementation: Leverage our in-house validation experience through scalable, turnkey solutions that streamline audit readiness and reduce operational burdens.
- Regulatory Compliance Assurance: Navigate FDA 21 CFR Part 11, EU Annex 11, ICH E6 "GCP" (R3) ISPE GAMP5 2nd edition and other global regulations with confidence using our validation frameworks and documentation expertise.
- Customized Validation Frameworks: Tailored risk-based CSV strategies that align with your unique systems, workflows, and risk profiles while maintaining agility for evolving clinical needs.

"Our CSV services are your shortcut to using the system of your choice while maintaining regulatory compliance and audit readiness."

Dr. Sylvia Philipp
Head of QA-IT

IT Application Management

Your Reliable Partner for Pharma IT Solutions

At elderbrook solutions, we specialize in IT Application Management tailored for the pharmaceutical industry. We ensure your IT applications are managed, maintained, and continuously developed throughout their entire lifecycle - so you can focus on your core business.

Our Service Portfolio:

- Full Lifecycle Support: From the initial idea to procurement, technical deployment, daily operation, and secure retirement, we manage every phase of your application's journey.
- Process Optimization: We help you optimize, extend, and connect your systems, ensuring seamless integration and efficiency across your digital landscape.
- Expert Support & Training: Our team provides ongoing support, user training, and quality assurance, so your staff can work productively and securely.
  Single Point of Contact: With elderbrook solutions, you have one reliable partner for all your IT application needs - transparent, efficient, and always accessible.

Your Benefits:

- More IT support in everyday operations
- Efficient and transparent processes
- Greater involvement in shaping your digital workplace
- One central contact for your entire IT system landscape - true added value for productive work

  Let's advance your pharmaceutical business with secure, user-focused IT solutions.

Julia & Sarah Esmezjan
IT Application Managers

Archiving

Long-term, secure storage of GxP-relevant information and data in a controlled, compliant environment.

Our archiving services refer to the systematic, secure, and compliant storage of GxP- (and especially GCP)-relevant documents and data, ensuring long-term preservation, traceability, and regulatory readiness. These services are essential across all regulated domains - GMP, GLP, GCP, and pharmacovigilance.

Some key characteristics of GxP-compliant archiving are:

- Controlled environment for example: Humidity
- Data integrity & security e.g. Compliance with ALCOA++
- Retention Periods e.g. Defined per regulatory requirements
- Regulatory Frameworks coresponding to international regulatory standards (ICH Guidelines, ISO standards, EU GMP Annex 11, 21 CFR Part 11)

We offer advice and support on:

- Planning, development and management of a paper archive, a digital archive, a hybrid archive
- Written formulation of your archiving process (incl. SOP, WI, Retention
- Schedule, Destruction Policy, etc.)
- Development of a long-term preservation strategy
  Introduction and validation of software for electronic archiving
- Data migration in and out of archiving systems

"The archive is the memory of an organization; it constitutes its identity and helps it shape its future."

Dr. Karin Ludewig
Archivist & Information Governance Expert

We are elderbrook solutions!

elderbrook solutions GmbH is a German Contract Research Organization established in 2013, specializing in biostatistics, clinical data management, statistical programming, clinical software development, and project management.

From our founding in Langenargen to our current headquarters in Bietigheim-Bissingen, we have grown to encompass a team of approximately 200 full-time experts complemented by specialized freelancers across 24 countries on 5 continents.

Our German roots are reflected in our commitment to exceptionally high quality standards, rigorous methodologies, and precise execution. We are driven by the concept of “linking minds”, enabling cross-disciplinary collaboration that produces innovative solutions for complex clinical challenges.

Our expertise in clinical systems, data management, and data analytics allows us to deliver actionable insights that optimize clinical trials for pharmaceutical, biotechnology, and medical device companies.

With elderbrook, clients gain a partner committed to excellence at every stage of the clinical development process.

Get in Touch with us.
Your Partner in Excellence.

Our team is always ready to respond to your inquiries with the attentiveness and expertise you deserve. We understand that in the fast-paced world of clinical development, timely responses and agile solutions make all the difference.

When you contact elderbrook solutions, you're not simply submitting a query - you're initiating a conversation with experts who understand your challenges and are committed to finding the right solution for your specific needs.

Personal Connections Matter
We firmly believe that behind every project and every data point are people who matter. That's why we prioritize building genuine relationships with our clients through friendly, attentive communication. Our team is always available to schedule calls, video conferences, or even in-person meetings when needed.

Our agile approach means we can adapt quickly to your changing needs while maintaining the reliability and quality you expect from a trusted partner.

Contact us today to experience the elderbrook difference - where quality, agility, and personal attention combine to create exceptional outcomes for your clinical development needs.

"We are guided by the needs and wishes of our customers"

Andre Kohlstadt
Client Aqcuisition Manager

Tel: +49 155 60 60 911 2
connect@elderbrook.de

elderbrook

linking minds

www.elderbrook.de

Trusted Partnership with:

Veeva viedoc™