

FORMEDIX - THE CLINICAL DATA ARCHITECTS

Formedix is a leading provider of pharmaceutical standards-based software for the conception, generation, delivery and integration of electronic and paper-based clinical trials. By eliminating paper (where appropriate) and building upon industry data interchange standards introduced by the Clinical Data Interchange Standards Consortium (CDISC), Health Level 7 and other standards organisations, powerful Formedix software technologies significantly reduce the cost of clinical trials and (more importantly) their duration, which is the critical path in drug development.

As well as developing cutting edge software, Formedix also offers a comprehensive range of consultancy, training and implementation services. These build upon the experience and expertise we have acquired whilst developing and deploying innovative standards-based products and services for our clients. Formedix are active participants on the CDISC Industry Advisory Board and Strategic Task Force, and our in-house experts have over 15 years of data standards experience. We are ideally placed to deliver a range of services, whether it be early adoption strategy planning, business impact assessments or the introduction of new technologies for study specification, data transport or archiving. In short, we can assist and support you with products and services wherever and whenever you want to adopt standards within your clinical development lifecycle.

OUR VISION

Historically there has been no established industry standard for the exchange of metadata (data about data) or data collected during clinical trials. Many existing practices related to specifying and sharing of trial specifications amongst internal and external collaborators manifest high error rates, laborious working practices and elongated review and approval cycles. Even today, clinical trial set-up involves the creation of a range of content types (such as protocols, case report forms, data management plans, analysis plans, annotated case report forms, case report tabulations) by multiple role-players, sometimes working in isolation from colleagues. The majority of this information is unstructured and resides in disparate locations in different formats - Microsoft Word files, Lotus Notes databases, within content management solutions such as Documentum and so on. Formedix is dedicated to the development of trial authoring and specification tools that utilise the CDISC Operational and Submission Data Models and intelligent structured XML documents to produce a cohesive trial specification. We believe that until this becomes a reality, existing technologies will place considerable constraints on content reuse and interoperability resulting in duplication of effort and increased trial set-up duration and cost.

Formedix believes the future of clinical data management lies in the successful implementation of data standards technologies that will become the "glue" between proprietary clinical processing and analytical software used today. With this vision we have based all of our products on open data standards, protecting your technology investment now and in the future.

OUR PRODUCTS

Formedix Origin is a unique family of trial authoring and specification tools and our first product, Origin Study Modeller, is the only dedicated multi-user tool that allows a study design team to rapidly and collaboratively define the content and structure (metadata) of their clinical databases and output these designs in the vendor neutral Operational Data Model (ODM) format. Pharmaceutical, medical device and biotechnology companies can now read, edit, define, share and manage database specifications both internally and amongst external partners. Origin Study Modeller streamlines study specification to markedly decrease upfront study set-up, and promotes efficient team working which eliminates elongated review and approval cycles. This software has been in development for over two years and has already been successfully trialed by a number of pharmaceutical companies. Benchmarking data from these trials shows that by using Origin Study Modeller an average 50% reduction in trial specification time is achievable.

Formedix Transform utilises CDISC ODM and XML specifications generated by Origin, rapidly building Electronic Data Capture (EDC) databases using high-speed translators and program-generative techniques. Elimination of costly, error prone manual coding gives us the capability to deliver on time, every time. The use of these technologies in recent EDC studies has demonstrated an average four-fold reduction in database build time.

Formedix Express is an EDC solution that can operate in a connected or disconnected mode and delivers features such as Autoguiding, real time concurrent data capture and support for biometric signatures. Formedix has designed Express to allow maximum data input in minimal time.

Every data value in Express can be exported to a populated ODM file. Companies can now choose an EDC system where their data is portable and can be read and moved anywhere now or in the future. Consequently, your clinical data and metadata is no longer tied to the particular version of the proprietary EDC or clinical data management software you are using today or the upgraded version you may be using tomorrow.

OUR SERVICES

Formedix realises it's not just about the technology but about understanding how that technology will impact on your current operations and in-house processes. From trial specification through content management and data transport, Formedix experts have developed processes and management techniques that will facilitate the introduction of standards within your organisation.

Our consultancy practice provides comprehensive education, implementation and software development services as well as advice and guidance on business re-engineering and return on investment projections for clients who are considering migrating to CDISC data standards.

ABOUT FORMEDIX

Formedix has invested extensive time and resource in leading-edge standards-based electronic trial solutions. Priding itself in it's team of dynamic and experienced software engineers, Formedix has won two industry awards for technical excellence and has derived a market leading position through consistent technical innovation, with best-of-class performance with its Origin product suite. The company has offices in Glasgow, Scotland and Burlington, Massachusetts.

CONTACT US

To learn more about Formedix products and services please e-mail us at wecanhelp@formedix.com, or visit us online at www.formedix.com



Suite 3001, Mile End, Abbey Mill, Seedhill
Paisley, UK, PA1 1TJ

☎ Tel: +44 (0) 141 561 4150
☎ Fax: +44 (0) 800 781 6192

35 Corporate Drive, 4th Floor, Burlington
MA 01803 USA

☎ Tel: (+1) 781 685 4995
☎ Fax: (+1) 781 685 4601

www.formedix.com
wecanhelp@formedix.com