

Working Together to Implement Standards in your organisation

ADVISING, ASSISTING AND SUPPORTING YOU THROUGHOUT DATA STANDARDS ADOPTION

Formedix offers a comprehensive range of consultancy, training and implementation services incorporating the experience, expertise and knowledge we have acquired whilst developing and deploying innovative standards-based products and services for our clients. Active participants in the Clinical Data Interchange Standards Consortium (CDISC) and other standards bodies, our in-house experts have over 15 years of data standards experience. We are ideally placed to deliver a range of services that encompass all your needs, 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 you wherever and whenever you want to adopt standards within your clinical development lifecycle.

COLLABORATIVE CUSTOM DEVELOPMENT

Formedix is the developer of Origin, the first trial authoring and specification suite based on CDISC data standards, and is uniquely positioned to provide in-depth development expertise. We offer a range of software development services such as custom visualizations and reporting, XML schema development, business rule extensions, integration with in-house content management systems, and customised plug-ins and add-ons that extend our existing products to meet individual client requirements. Our approach is to share our standards and XML knowledge with your personnel and collaborate closely so that we can deliver custom software that exactly matches your requirements and follows a controlled and well-defined software development lifecycle.

BUSINESS PROCESS ASSESSMENT, PROCESS IMPROVEMENT AND MAXIMISING YOUR RETURN ON INVESTMENT

It's not just about the technology. It's 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 has developed processes and management techniques that will facilitate the introduction of standards within your organisation.

Our aim is to optimise your internal processes by every means possible and maximise your return on investment. This may involve recommending complimentary products and services from other vendors; if so, we are happy to help so that your complete clinical trial lifecycle is streamlined - from specification to archive.

INTRODUCE STRUCTURED XML CONTENT INTO YOUR CLINICAL DEVELOPMENT

Presently, 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 and 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 believes that this unstructured content must be migrated to an intelligent structured XML format in order to capitalise on content reuse and interoperability opportunities, thus delivering time and cost savings in the study setup process. As a result, Formedix has introduced a range of services, which include advising on technology choices for in-house conversion activity, development of XML languages for existing content, and conversion of your existing content to XML and CDISC Operational and Submission Data formats.

IMPLEMENTING EFFECTIVE STANDARDS-BASED CONTENT MANAGEMENT SOLUTIONS

Implementing enterprise-wide data standards libraries rich in reusable content within your organisation goes way beyond simply purchasing and installing the software. Formedix recognises this and can provide personnel versed not only in current data management methods but fully conversant with existing and new data standards, intelligent XML document technology and advanced indexing, referencing and linking technologies. Engaging our personnel and following a logical, staged implementation strategy will ensure you maximize your data standards investment and deploy your software and hardware systems seamlessly and effectively.

LEGACY DATA CONVERSION UTILISING CUSTOM IMPORTERS AND EXPORTERS

Standards adoption will inevitably involve conversion of obsolete or existing clinical data and metadata (data about data) to portable, vendor neutral, system independent formats such as the CDISC Operational Data Model. Formedix has extensive experience developing specialist laboratory data importers and clinical data exporters for our electronic data capture solution, Express. Call us and we will be happy to help with your data conversion project.

TRAINING AND EDUCATION SERVICES

Formedix's team of experienced training personnel can deliver a comprehensive range of training packages, which cover a wide variety of topics and are suited to novice and data standards professionals alike. Our introductory courses describe where and how CDISC standards might be used and our advanced courses explore the individual data models in depth, covering topics such as dependencies and links between the models, vendor extensions and so on. Tailored training programmes can be produced on request and we are happy to deliver our courses as one-on-one individual training, group training either at our premises, at your facility or at a location of your choice.

ABOUT FORMEDIX

Formedix develops enterprise pharmaceutical software solutions 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 such as CDISC, powerful Formedix software technologies significantly reduce both the cost of clinical trials and (more importantly) their duration, which is the critical path in drug development.

Formedix is a world-leader in delivering electronic trial solutions which utilise standards-based trial designs, automated EDC system generation, advanced workflow technologies and secure data networks. These solutions enable the gathering and dissemination of data globally, on a daily basis, enabling pharmaceutical companies worldwide to re-engineer and streamline their trial processes. Formedix customers include market leading pharmaceutical companies in the UK, USA and Europe.

Formedix has invested more than \$3million in standards-based electronic trial solutions, and has won two awards for technical excellence and innovation. The company has obtained a market leading position through consistent technical innovation, delivering best-of-class performance with its Origin technology.



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