PhUSE 2017

Paper FDX01

Software Demonstration

Formedix On: A Powerful Platform to Accelerate Clinical Trials

Kevin Burges, Formedix, Burlington, MA, US

ABSTRACT

Following a pivotal 2017 release, our clinical trial platform – Formedix On – boasts exciting new features and functionality centered on metadata management, organizational standards management, and on demand digital services for simplifying the creation of submission deliverables.

INTRODUCTION

Mid-2017 will see Formedix present a major new release of Formedix On, the clinical trial platform that is designed to accelerate clinical trials.

The release will include a central repository for storing and managing all your metadata, across the end-to-end lifecycle of your studies. Enhanced functionality to manage your organizational standards will also be introduced, helping you to increase data quality. Home to a collection of on demand digital services, Formedix On also boasts automated services for dataset conversion, generating Define-XML files from SAS transport files, and publishing Define.pdf files from Define-XML.

CENTRAL REPOSITORY

Your whole team can now access all your studies and organizational standards in one place, on the web. Powerful global search functionality makes it easy to find studies, standards or assets in your repository.

END-TO END STUDIES AND STANDARDS

Simplifying the management of studies, all of your study metadata including forms, edit checks, datasets, mappings, terminologies and files, is stored in one place.

Dataset mappings can be specified, describing how to get from your EDC data to your submission data and linking your assets across the trial lifecycle.

You can define and maintain organizational standards that can be used to build studies, increase data quality and reduce design time. Standardizing variations of assets for specific therapeutic areas further increases the efficiency of your study design process. Any deviations between studies and organizational standards are highlighted, making it simple to conform to standards.

Enhanced document and link functionality is also introduced, meaning all your study collateral can now be kept in one place. You can manage any files related to a study or standard such as the protocol, EDC test plan, statistical analysis plan, study data reviewers guide or instructions on how to use a standard. If you already manage files in a document management system then you can link to those files directly from your studies or standards.

ADVANCED VISUALIZATIONS

Advanced visualizations of your assets such as eCRF screens, edit check and mapping specifications, and annotated CRFs can all be accessed on the web by your teams at any time. You have instant visibility of how your forms will look in your chosen EDC system, before you build your study.

MULTI EDC INTEGRATION

Unique integrations with the leading EDC systems allows users to design their entire study within Formedix On. Choose your preferred EDC system and automatically build the EDC database at the click of a button. The platform is seamlessly integrated with 7 EDC systems including Medidata Rave and Oracle InForm.

DATASET CONVERSION

Formedix On makes it simple to generate your submission datasets. Your data is already mapped in the study design, so you can run your conversions as soon as your data starts coming in.

ON DEMAND DIGITAL SERVICES

Our collection of on demand digital services automate various useful tasks, such as:

Generate Define-XML files from SAS transport files: Formedix On makes it easy and quick to convert a set of SAS Transport (XPT) files to a Define-XML-compliant file. It creates Define-XML metadata from a set of SAS XPT files, including terminologies and value lists.

Publish Define.pdf files from Define-XML: As the name suggests, Formedix On can automatically create a Define.pdf file from your Define-XML file.

Convert Rave study designs to ODM: Allows existing Rave studies to be easily loaded into Formedix On, complete with full form layout, edit checks and visit matrices.

CONCLUSION

Advocates of upfront adoption of CDISC and organizational standards, we have designed the Formedix On platform to support this, enhancing data quality, reducing design time, and promoting reuse across trials. New features and functionality within the Formedix On platform highlight areas where significant time, cost and process efficiencies can be realized across your clinical trials.

CONTACT INFORMATION

(In case a reader wants to get in touch with you, please put your contact information at the end of the paper.)
Your comments and questions are valued and encouraged. Contact the author at:

Author Name: Kevin Burges
Company: Formedix
Address: 1500 District Avenue
City / Postcode: Burlington, MA 01803
Work Phone: +1 781 685 4995
Email: kevinburges@formedix.com
Web: www.formedix.com

Brand and product names are trademarks of their respective companies.