



# Velos eResearch Data Management

*A configurable and easy-to-use form designer leverages a powerful, multi-organization security infrastructure to ensure a 21 CFR Part 11 compliant, scalable and robust deployment, rapid study setup, and controlled online access for all participants.*

## Velos eResearch Product Line

- Velos eResearch
- Account Management
- Study Setup
- Data Management
- Patient Management
- Reports & Ad-Hoc Queries

- Velos eClinical
- Velos eFinancials
- Velos ePortal
- Velos eIRB
- Velos eSample
- Velos eCardio
- Velos eOncology
- Velos eTools

## Technology-based Services

- Velos Grid Services
- Velos Interface Engine

## Contact Information

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The screenshot displays a web-based form with several sections. At the top, there are input fields for 'Present at Site Visit' (Site Personnel, Endpoint Personnel, Sponsor) and 'Enrollment Status' (Planned, Screened, Active in Screening, Screening Failures, Randomized, Active in Treatment, Completed, WD after Rand, WD for AEs, WD for Other). Below this is a 'SINCE LAST VISIT' section with a list of items (1-6) and corresponding input fields. The 'Pain Intensity' section features three horizontal scales: 'How bad is your TYPICAL or AVERAGE pain?' (value 32), 'How bad is your pain when it is AT ITS LEAST?' (value 21), and 'How bad is your pain when it is AT ITS WORST?' (value 74). Each scale has 'No pain' and 'Worst possible pain' markers. A legend below the scales defines 'Pain Intensity' levels from 1 to 6, and 'Personal Care (e.g., Washing, Dressing)' levels from 1 to 3.

At the heart of Velos eResearch Data Management is a powerful form and application designer. All data sets created with the form designer are directly accessible in an integrated ad-hoc query module, which in turn supports file exports to SAS, Word, Excel, or third party Business Intelligence applications. Specialized query management and related reporting capabilities enable online query identification, communications, review, and resolution.

## Form Designer and Library

Velos employs a structured library system for management of forms, dictionaries, data variables and their attributes. All library items can be stored, searched, copied, reused, and archived, and are controlled by access privileges. Velos eResearch, in general, and the form designer module specifically, is designed for ease-of-use. Users do not need specific programming skills to design electronic case report forms (eCRFs). Internationalization is supported in a number of ways ranging from incorporation of specific dictionaries to designing forms in different languages.

## Form Versioning

Form changes are tracked in the audit trail and a history of the changes can be viewed at any time. Each eCRF is available to be viewed, printed (blank and completed) or edited, as required, and the appropriate version is presented to the user. Data entry into the eCRFs is facilitated through the presentation of the appropriate form for the corresponding visits, and lockdowns can be performed at several levels, e.g. form, patient or study.

## Discrepancy Management

Numerous data items and edit checks can be included in a form such as Multiple Choice Fields, Edit Fields (Date, Text or Number), Links, Comments, etc. Examples of Edit checks range from those that can be applied on individual variables (e.g. number range, mandatory flag), to those that work across variables (e.g. skip patterns or calculated fields). System-generated queries, manual queries and prompts provide assistance in data entry and help ensure good quality data.