

Project: Protocol Authoring Tool (MS Word + XML)

- Description:** Fast Track Systems wanted a novel application that allowed clinical users to write trial protocols in a familiar Word environment, while key trial data was encoded in XML. This system had to handle a flexible user workflow, arbitrary client configuration, while being standards (ICH E6, 21CFR part 11) compliant.
- Goal:** Create a protocol design application that would maximize user acceptance and benefit.
- Approach:**
- Interviews with subject matter experts (in-house and clients)
 - Iterative prototyping with Engineering to determine technical feasibility. (Integration with Word was difficult.)
 - Ongoing user testing with development builds to assure user acceptance
 - Onsite observation of users working with application to develop list of enhancements for next release
- Results:** Application designed and built on schedule, despite complexity and technical challenges
Positive user feedback during training and use

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The main window displays a Microsoft Word document titled "Protocol Designer - PX231F: Phase III - Rheumatoid Arthritis (Author: Marion Smith MD)". The document content includes sections for 4.4 Endpoints (Primary, Secondary, Tertiary efficacy) and 5 Study Population (Number of Patients, Number of Centers). A callout box states: "The body of the protocol is edited in Word using familiar tools and methods. Word editing metaphors were extended to leverage user knowledge to new situations."

The "Protocol Design Guide" window is open, showing a table of test articles and a "SOA: Treatment Arm" grid. The test article table is as follows:

| Test Article | Type | Role | Route | Formulation | Dose | Strength |
|--------------|------|--------------|-------------|-------------|--------------|----------|
| VX234-4 | drug | test article | intravenous | ampule | 500 mg every | 500 mg |
| Phlegmase | drug | comparator | oral | gelcap | 250 mg | 125 mg |
| Mucomyst | drug | adjunct Tx | inhaled | inhaler | 2 puffs | |
| Bronchoblast | drug | comparator | oral | tablet | 1 tab | 10 mg |

The "SOA: Treatment Arm" grid shows visits (W1-W130) and associated tasks with their costs. The cost summary at the bottom indicates: "Cost for selected Visits: \$2,121" and "Total cost per patient: \$8,975".

A callout box at the bottom states: "A 'Protocol Design Guide' steps users through the collection of critical trial data, and the association of those elements to each other."

The "Task-Visit Detail" dialog box is shown for "Hand X-Ray / Week 52". It includes fields for "Detail Text" (Pronated and supinated views), "Footnote" (auto-added) with checkboxes for "Have patient stand during examination and during venipuncture" and "Radiographs will be taken using Ektascan-B RA single emulsion film and Lane", and "Lab Info" (Central Lab checked, Local Lab unchecked). The "Task-Visit Purpose" section has dropdowns for Purpose (Safety, Efficacy, Other), Safety/Efficacy Outcome (Structural Joint Damage), and Other Purpose (regulatory). It also includes "Add Task-Visit Purpose" fields and "Add to List" / "Delete" buttons.

Detail dialogs allow user to drill down to additional detail.