Principles for Enhanced Recruitment of Subjects in a Large Clinical Trial: The XENDOS Study Experience

Jarl S. Torgerson, MD, PhD, Krister Arlinger, MSc, Marcus Käppi, MSc, MBA, and Lars Sjöström, MD, PhD
Department of Body Composition and Metabolism, Sahlgrenska University Hospital, Göteborg, Sweden

ABSTRACT: In most clinical trials it is problematic to recruit enough patients within a reasonable time period. Prolonged or inefficient recruitment or both can have negative scientific and economic consequences. The XENDOS (XENical in the prevention of Diabetes in Obese Subjects) study is an ongoing randomized, double-blind, placebo-controlled, prospective, multicenter trial investigating whether orlistat combined with hypocaloric diet and moderate physical exercise can reduce the incidence of diabetes in obese subjects. To implement the XENDOS protocol and recruit the study patients, we designed a system for centralized patient recruitment and centralized scheduling of patients and staff at the 22 collaborating centers. The recruitment and inclusion phase was divided into a series of different consecutive examinations of increasing complexity. Relative simple initial examinations enabling a large throughput of patients were followed by more detailed examinations of fewer subjects, by then known to fulfil some of the study-specific requirements. With the aid of object-oriented techniques, the software was modularized to enable concurrent engineering. We also selected a structure where plug-in modules handling specific tasks could be added to the system as needed. The design was supported by a flow-oriented view of the progress of the patients through the study. With this overall solution we managed to include 3305 subjects (98.8% of the requested number) within less than 4 months. The sex distribution (44.8% men) and the number of patients with impaired glucose tolerance (IGT), (21.1%) were in close accordance with, or far better than, the requirements of the protocol (45% men, at least 10% IGT patients). The basic design of the XENDOS information system can be adapted to fulfil the requirements of other study protocols within the fields of obesity, diabetes, hypertension, coronary heart disease, etc. Shortening the recruitment and inclusion phase of large clinical trials is of great value both to be medical society and the pharmaceutical industry. Control Clin Trials 2001;22:515–525 © Elsevier Science Inc. 2001

KEY WORDS: Obesity, diabetes, pharmacological treatment, randomized clinical trial, multicenter trial, patient recruitment, surveillance of data, scheduling of resources.
Explore Litigation Insights

Docket Alarm provides insights to develop a more informed litigation strategy and the peace of mind of knowing you’re on top of things.

Real-Time Litigation Alerts

Keep your litigation team up-to-date with real-time alerts and advanced team management tools built for the enterprise, all while greatly reducing PACER spend.

Our comprehensive service means we can handle Federal, State, and Administrative courts across the country.

Advanced Docket Research

With over 230 million records, Docket Alarm’s cloud-native docket research platform finds what other services can’t. Coverage includes Federal, State, plus PTAB, TTAB, ITC and NLRB decisions, all in one place.

Identify arguments that have been successful in the past with full text, pinpoint searching. Link to case law cited within any court document via Fastcase.

Analytics At Your Fingertips

Learn what happened the last time a particular judge, opposing counsel or company faced cases similar to yours.

Advanced out-of-the-box PTAB and TTAB analytics are always at your fingertips.

API

Docket Alarm offers a powerful API (application programming interface) to developers that want to integrate case filings into their apps.

LAW FIRMS

Build custom dashboards for your attorneys and clients with live data direct from the court.

Automate many repetitive legal tasks like conflict checks, document management, and marketing.

FINANCIAL INSTITUTIONS

Litigation and bankruptcy checks for companies and debtors.

E-DISCOVERY AND LEGAL VENDORS

Sync your system to PACER to automate legal marketing.

WHAT WILL YOU BUILD? | sales@docketalarm.com | 1-866-77-FASTCASE