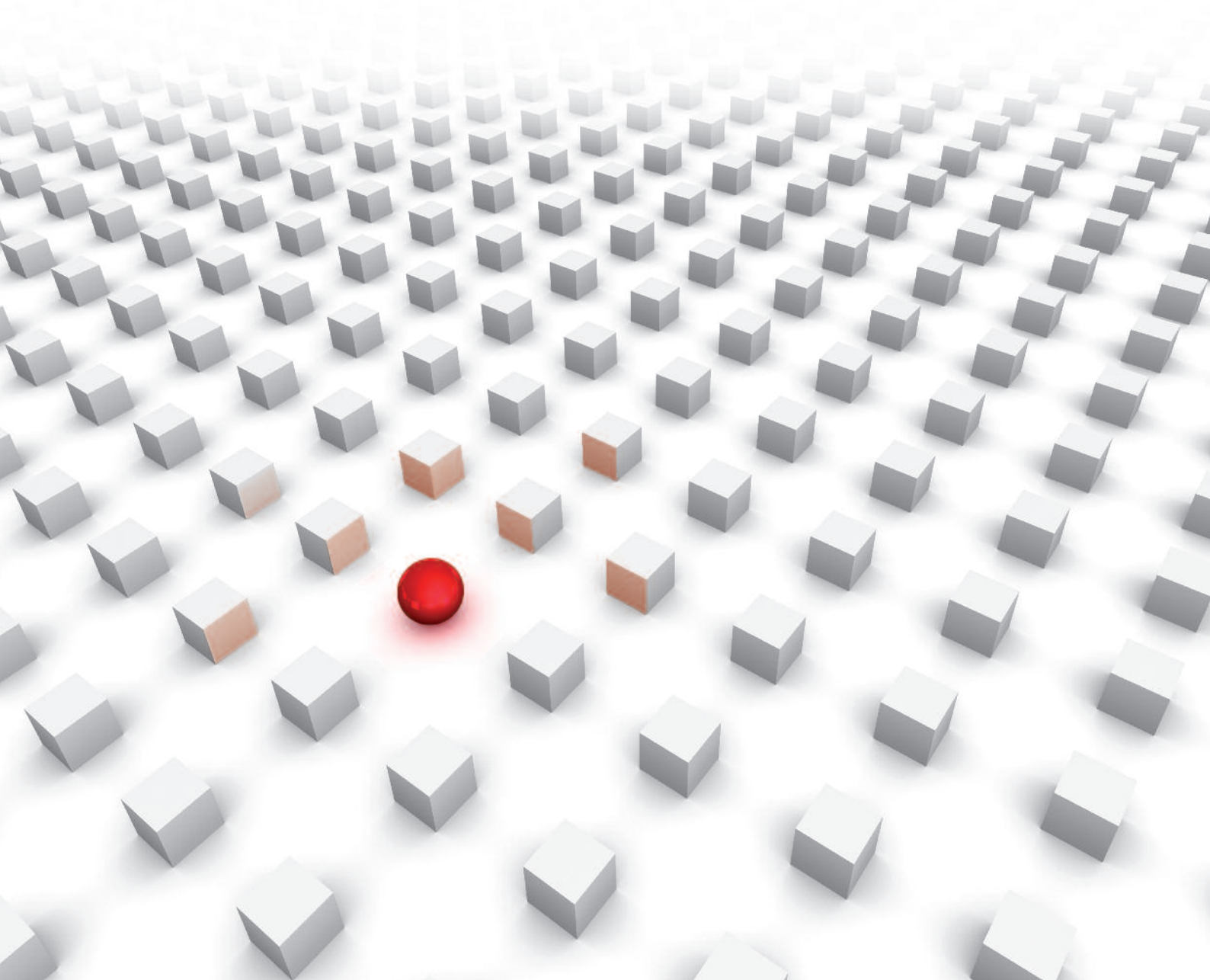


Clinical Trial Technology



HyperSuite®: Integrated Solution for a complete e-Study Management

Pierrel Research combination of clinical and technological expertise helps clients find better ways to conduct clinical research, and ultimately, to rapidly bring safe and effective new therapeutics and medical devices into the global marketplace. Pierrel Research integrated technology solutions for clinical trials help customers accelerate the drug development process through innovation. HyperSuite® is a web-based Platform to collect, access, exchange and archive data and documents required for the conduct, management, analysis and reporting of your clinical trials.

HyperSuite®, already used in more than 320 studies involving 18.186 investigators and recruiting 310.216 patients, provides our customers with the following benefits:

Faster time to market. The use of HyperSuite streamlines the clinical development process, enabling users to compress the time associated with implementing clinical trials and entering, cleaning and analyzing data.

Higher quality and visibility of results. HyperSuite allows users to enhance the quality and completeness of study data by providing real-time data cleaning and eliminating duplicative manual entry of data.

Complete eClinical Trial Solution. in addition to the functionalities for data capture, cleaning and reporting, HyperSuite includes fully integrated modules specifically designed for the management of drug supply, SAEs notification, ePRO, study documents and sms/fax communications with the investigators' team.

Improved investigator satisfaction. HyperSuite user interfaces have been designed to meet the needs of clinicians, with intuitive, consistent point-and-click navigation and a familiar clinical data entry approach. All modules and tools are deployed over the Internet and require no special skills to operate the system .

Centralized control of global trials. HyperSuite provides a single centralized and secure data repository that allows project managers to maintain regular and real time oversight of each site activity.

Multiple Trial Platform. A global library, prepared according to Sponsor's specific requirements, is used to manage study elements. It speeds up design of multiple studies through the reuse of previous studies or study components ranging from edit checks to entire forms and visit structures. HyperSuite® MTP reduces the time and costs required to set up a study, and promotes eCRF standards and consistency across multiple studies for the same sponsor.



The screenshot displays the HyperSuite web interface. At the top, there is a navigation bar with the Pierrel Research logo and a 'Sponsor name' field. Below the navigation bar, there are several tabs: 'Home', 'New patient registration', 'Registered patients', 'Find Patient', 'SUS CRF', and 'Drug Supply'. The main content area shows a 'Patient List' table with columns for 'Pat. Visit', 'Diary', 'Report', 'Patient Num.', 'Registration', 'Screening', 'Baseline', and a series of weekly visits (Week 12, Week 24, Week 36, Week 48, Week 60, Week 72, Week 84, Week 96), 'End of study', 'General section', and 'eSAC Report Form'. The table contains 10 rows of patient data, with various colored arrows indicating the status of each visit. Below the table is a legend with four items: 'Empty form', 'Some forms to be completed', 'Forms completed', and 'Skipped visit'. At the bottom of the interface, there is a 'System Information' section.

HyperSuite® Modules

Hypernet Hypernet (e-CRF) has been developed with the aim to be stable, secure and scalable and to facilitate the role of all staff involved in a clinical trial, anywhere in the world, with any computer, and through any internet browser.

Hyperline Phone (broadcast/mobile) and web-based Multimedia Messenger System to contact all or subgroups of study participants in a fast, one click, easy and secure way. It supports e-mail, SMS, fax, and a digitalized human voice (text-to-speech) scheduling and tracking all communications.

HyperSite-ePRO Web-based ePRO at site during clinical trial visits. Each investigational site is provided with a Touch Screen Device (Smart Phone or Tablet), that gets access via a Wi-Fi network or through a connect card to the study HyperSuite eCRF section, containing the specific questionnaires to be administered to that patient at that study visit.

PatientLink-IVRS Interactive phone-based patient's diary, that calls and speaks to the subject ("Text-To-Speech" technology) by means of a human digital voice. Dramatic increase in diary quality and compliance because of the automated call to the subject, according to the specific diary time schedule.

HyperIWRDS Integrated Web-based Randomization and Drug Supply System for centralized randomization and drug supply management. Dynamic subject randomization & dosing; Subject tracking and drug management; Tracking of clinical trial supply; Drug inventory management planning; Integration with Hypernet; Standard and customized reporting; Based on the randomization rate at each site and on the drug kits' expiry date, the system generates an automated "order notification" for the re-supply to the site.

Hyperfile Web-based eCTMF / eISF document management and archiving tool. Controlled access, secure storage, real time document availability, on-line statistics on missing documents, per centre and per CTMF/ISF section, and on time-delays from document issue date to document filing date.

HyperSAE This module allows the notification of a Serious Adverse Event (SAE) from the site to the responsible Pharmacovigilance officer. Instead of the traditional SAE fax form, the investigator fills in the SAE-related information into the eSAE Report Form. By electronically signing and submitting it, an immediate notification via mail is sent to all the appropriate recipients.

HypereDDE Web-based Double Data Entry (eDDE) module for paper or hybrid paper/EDC Studies. Paper CRFs are collected, scanned and uploaded into the appropriate eDDE module; Independent double data entry with an independent third party comparing data from the two entries and solving any discrepancies.

Ask for a free WebEx presentation of HyperSuite® functionalities writing to:
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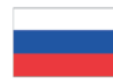


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