

# Initiator™

## Are you optimizing your Phase I unit's performance?

### Key features

- **Full-featured, Phase I trial management solution providing study design, recruitment, data collection and reporting functionalities**
- **Robust volunteer selection and tracking capability**
- **Comprehensive study setup including procedure scheduling, staff resourcing, label preparation and automatic eCRF generation**
- **Touch screen optimized for easy data entry**
- **Direct data capture from instruments and real-time access to trial data**
- **Task-driven workflow to ensure step-by-step guidance and timely completion of all study activities**
- **Complete management of samples including dispatch, tests and results including seamless integration with laboratories**

### Key Benefits

- Highly configurable to adapt to individual study/sponsor requirements and late protocol changes
- Single capture and storage of data eliminating transcription errors
- Streamlined workflow resulting in resource optimization and increased efficiency of study setup and operation
- Enhanced quality and integrity of data, enabling early and informed decision making
- Robust solution with a proven track record of over 15 years and a user base of over 1,500 users
- Bedside data collection technology ensures operational continuity regardless of network or server disruption
- Laboratory interface automates test requisition and receipt of results

### Proven Phase I Solution

As the number of new drugs entering the Phase I stage is projected to increase dramatically over the next 10 years, it is critical to ensure these studies are run as efficiently as possible to enhance the overall productivity of the drug development pipeline. However, Phase I studies present many challenges as they are typically conducted over a short time span, demanding a very tight timetable for all patient events and associated activities. Many tasks are not only labor-intensive, but also must be carried out in a time-critical manner.

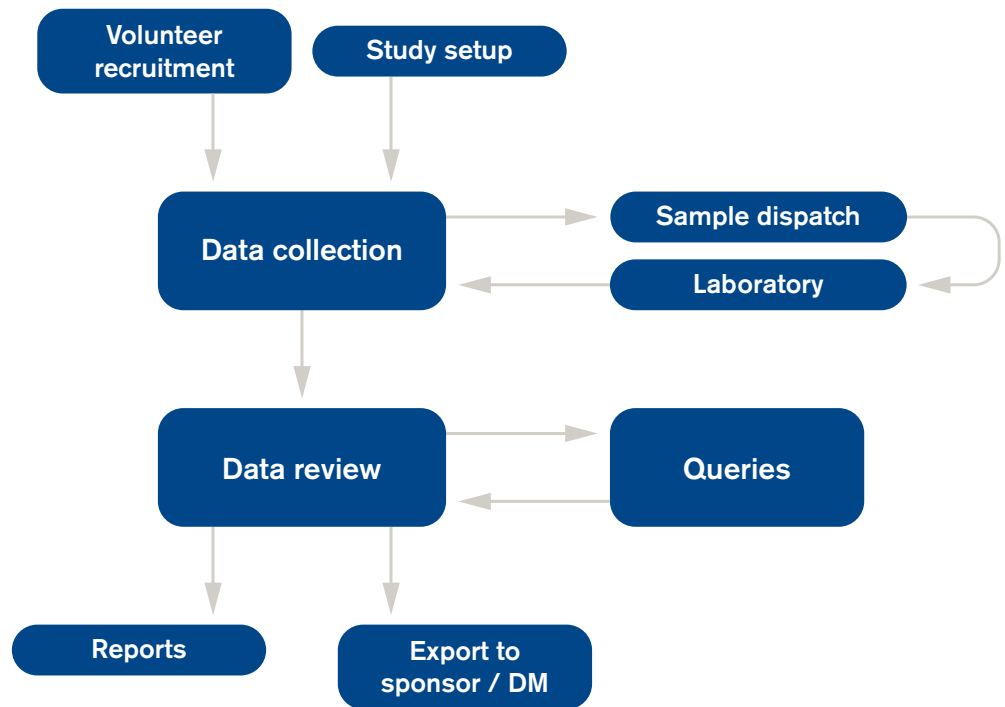
Perceptive Informatics' leading Phase I solution, Initiator™, is specifically designed to meet these unique needs of the early phase trials. Initiator is a complete Phase I solution that allows sponsors to effectively plan, manage and track every aspect of their early phase trials all within a single central application. It supports the entire study life cycle, all the way from recruitment to preparation of reports.

## Initiator™

Developed by proven experts with clinical and technology know-how, Initiator is highly configurable with built-in flexibility to support the individual requirements of your trial and rapidly adapt to any protocol changes. With a success record of over 15 years and a user base of over 1,500 users worldwide, Initiator is the proven solution of choice for many top pharmaceutical sponsors. Our solution has successfully helped clients to streamline processes, optimize the performance of their Phase I units and maximize efficiencies in the crucial early stages of their drug development programs. Why trust your study to anyone else?

### Making it Easy For You

At Perceptive, we understand the critical importance of making it easy for the study personnel to use trial technologies, and Initiator has been built with optimal usability in mind. Its comprehensive volunteer database, facilitating an easy selection of the appropriate subject population, allows a speedy and smooth trial start-up. Initiator's highly prescriptive, task-based workflow format makes it easy for your staff to perform all required activities at the right time, thereby ensuring all tasks are appropriately completed according to the



protocol. A consistent and easy-to-use data collection interface ensures that users can devote their time to their patients without being distracted by the software.

Initiator customers enjoy the services of a dedicated support help desk and an active and well-established User Group which promotes valuable knowledge-sharing and provides support to the wider user community.