

# IMPACT® CTMS

## My Sites – Site Management and Monitoring

The IMPACT® MySites module is a complete site management and monitoring tool for both office and field-based monitors.

A view of recruitment and issue activity across all sites assigned to a monitor allows an intelligent assessment of their workload to help plan site visits.

### Workload Management

The IMPACT MySites module supports all aspects of site management—monitoring, milestone planning, issues, and recruitment. The application offers a display of all the sites for which a given user has responsibility, in order to help them plan their workload intelligently. For instance, they can sort by the sites with the most open issues, by those who have had the most patients recruited since their last visit, and by those who have the highest predicted "patient visit workload". Drill down to the relevant maintenance and reporting screens allows them to update information and carry out site visits.

My Trial Units						
Trial Unit	Trial Unit Status	Expiry Date of IRB/IEC Approval	Number of Patients (Actual/Planned)	New Patients	New / Potential Visits	Open Issues
201/FRA/1	<a href="#">▶ Trial Unit Closed</a>		54 / 50	54	834 / 1	5
209/USA/8	<a href="#">▶ Ethical (IRB) Approval</a>	13-Jun-1999	0 / 8	0	0 / 4	0
209/USA/9	<a href="#">▶ Ethical (IRB) Approval</a>	22-Nov-1999	0 / 8	0	0 / 2	0

The MySites module is both an online and offline software tool. It continually synchronizes with the main IMPACT database, and only when the monitor indicates that he or she is about to conduct a site visit will the synching "pause". If offline, the monitor is offered the opportunity to accept updates and resolve discrepancies when they move to the online state. On completion of the visit, the monitor is given the opportunity to reconcile any additional patient or site data that may have been updated in the meantime.

On arrival at the site, the monitor views a patient task list that highlights new patient visits and work still to be carried out on current patients, as well as the visit task list which contains all general visit tasks required by their company SOPs.

The MySites module allows a monitor to record:

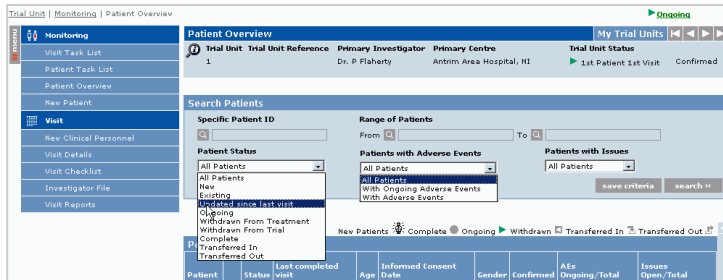
- General comments on the site's status and GCP compliance, using company- or trial-specific checklists.
- Visit details – who was seen by whom, what was discussed, the date of the next planned visit.
- Patient details, such as CRF and randomization number, date of birth, date of informed consent, visit dates, issues arising, adverse events, withdrawals, CRF page collection, patient histories, and concomitant medication. Where detailed patient information is not being collected, summary details can be recorded.
- CRF page queries and source data verification comments.
- Details of any new issues that have been recorded during the visit, along with updates of any outstanding issues which were raised at previous visits or at head office.
- Information about new personnel at the site.
- Dates for key milestones for the trial site.
- Documents present in the investigator study file, with comments as appropriate.
- Additional narrative text for the visit report.

The level of detail that a monitor is asked to record can vary depending on the necessities of a particular trial.

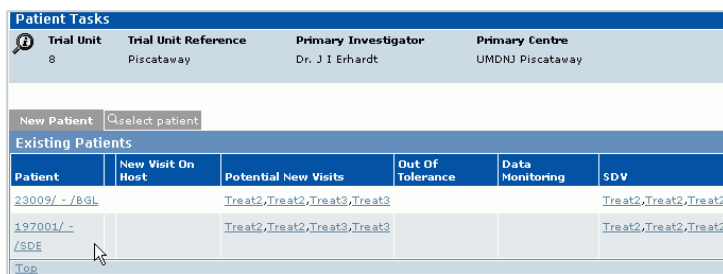
As the IMPACT Suite is often integrated with Electronic Data Capture (EDC) and Interactive Voice/Web Response Systems (IVR/IWR), data that has been imported can be highlighted for the monitor so that it can be verified on site. Any patient visit dates which lie outside acceptable tolerances are automatically flagged.

# IMPACT® CTMS

## Patient View



## Patient Task List



## E-signed Trip Reports

All the information recorded by the monitor is automatically combined into a monitoring visit report which is electronically signed by the monitor (considered 21 CFR Part 11 compliant). The structure of the monitoring visit report may be customized on a trial-by-trial and/or country-by-country basis. The report enters a configurable review cycle, with all comments and versions held in the IMPACT database.

All of the updated site data are synchronized with the main IMPACT database to update trial recruitment and contact details. Key dates and statuses are updated as appropriate. A reconciliation process avoids data conflicts between the offline MySites module and the central database.

## Produce Visit Report

Produce Visit Report								
Template Name	Mandatory	Report Name	Lastest Version	Report Produced Date	Produced By	Start Review	Review Status	New Version
Monitoring report with all data to date	No	209_usa_8_1_alltodate.pdf		22-Sep-2006	Mr. J Dietz	Start Review		New Version
Monitoring report with this visits data	No	209_usa_8_1_visit.pdf		22-Sep-2006	Mr. J Dietz	Start Review		New Version

## Site Management

Monitors can also update other aspects of their sites – contacts, recruitment, milestone dates – without being at the site. The MySites module is a 24/7/365 tool for sponsor site managers. In addition, personnel from contract research organizations (CROs) can also be allowed access to the module, ensuring monitoring harmonization across the trial.

## MySites on a USB Drive

MySites can also be deployed on a USB drive increasing portability and convenience for traveling monitors. Leave the laptop at home and work anywhere, anytime. With no need for lengthy IT deployment, just plug the drive into any computer and the MySites software will start. MySites data and application are safely encrypted on the USB drive preventing data corruption or malicious intrusions.

MySites on a USB drive allows standardization on a single monitoring tool across various monitoring providers (in-house monitors, global and regional CROs). It enables a network of providers without costly system integration. By standardizing your monitoring tool, you can improve data quality and consistency. One single system is able to capture all your monitoring activities, removing the need to go back and forth between spreadsheets, custom databases and other systems. Standard monitoring reports can be deployed across the whole monitoring team, with no need for retyping or reformatting of reports from external monitors.

## Perceptive at a Glance

Perceptive Informatics brings together exceptional clinical knowledge, experience and leading-edge technology. As the industry's leading eClinical solutions provider, we combine these qualities into a portfolio of business support applications and complementary services that optimize the process of product development and commercialization. Our customers are forward-thinking pharmaceutical, biotechnology and medical device companies, CROs and associated service providers.

Our versatile, comprehensive eClinical suite is built upon six areas, each of which makes extensive use of innovative technology:

**ClinPhone RTSM • Imaging • CTMS  
EDC • ePRO • Solutions**

Each element of our eClinical suite is designed to deliver practical and tangible results—decreasing the time, cost and risk associated with the development and launching of new products.

It is reassuring to know that our professionals have a combined clinical and technology background. This means that our products and services accommodate the needs of the regulated world (such as computer system validation and 21 CFR Part 11).

Our tried and tested solutions are used by many of the world's leading pharmaceutical companies.

**To learn more about how our solutions can help you, please contact us at [info@perceptive.com](mailto:info@perceptive.com).**