

IMPACT® CTMS

Clinical Supplies Tracking

The IMPACT® Clinical Supplies Tracking functionality can be used to ensure that the correct trial supplies are available at sites at the right time.

Dispatches, batch numbers and expiry dates can be recorded. This information can be used if a particular batch needs to be recalled or to identify sites with supplies that are about to expire.

Clinical Supplies Forecasting

Clinical supplies forecasting allows a company to define the supplies requirement for a trial. As trials progress, the supplies requirements may change and so the forecast can be revised accordingly. The quantity of both specific supplies items and patient packs can be recorded.

IMPACT can be used to calculate a forecast based on the patient visit design and planned number of patients. The supplies items required at each patient visit can be rolled up to a per-patient requirement; alternatively, the requirement can be entered directly. This is then multiplied by the number of planned patients, to calculate the overall trial requirement. In addition, randomization ratios and overages can be specified.

Site-level supplies can also be forecasted with warnings if certain 'renewable' items are sent to a center that has received them before.

Alternatively, the total requirement of supplies items for the trial can be recorded at a summary level.

The forecast can be projected over time. Users can break down the forecast by period (i.e., by quarter or by month) or using the enrollment plan for the trial. Approval of forecasts can be recorded on IMPACT. New versions of the forecast can be created as plans change.

Tracking Summary

Supplies available for dispatch – Details of supplies items that are ready to be sent to site including batch reference, quantity, manufacture and expiry/retest dates may be recorded.

Trial Unit Dispatch			
Total Number	276	Trial Alias	HEPTAN-TT-5
Trial Unit	301	Trial Description	Kaletra-heptanavir-d4T study
Dispatch Number	1	Primary Investigator	Dr D R Pugmire
		Primary Centre	Vancouver Hospital
		Dispatch Status	Planned
		Trial Country	Canada
		Trial Unit Status	▶ Lit Patient Lit Visit

Dispatch Details			
Planned Dispatch Date	4-Feb-2004	Planned Delivery Date	3-Feb-2004
Actual Dispatch Date		Actual Delivery Date	
Shipment Reference		Date Dispatch Note Printed	
Carrier Reference	UPS	Telephone Numbers	610-955-6548
Delivery Address	Clinical Trials PharmacD, Central Pharmacy, Block 14, Vancouver Hospital, 1200 Smithson Street, Vancouver, British Columbia V6C3B5	Telephone Numbers	799-955-2287
		Fax Numbers	610-955-6549
		Fax Numbers	799-955-5567

Dispatch – A dispatch records the movement of supplies from the organization, for example a country storage unit or subsidiary to a trial unit.

A dispatch can be set up and the supplies that are to be sent out can be allocated to the dispatch. Once the supplies have been dispatched, the actual date of dispatch, courier details and the batch references are recorded. The date that the supplies are received at the trial unit may also be noted.

Year 2004															
Monthly Breakdown															
Supplies Item	Jan 2004	Feb 2004	Mar 2004	Apr 2004	May 2004	Jun 2004	Jul 2004	Aug 2004	Sep 2004	Oct 2004	Nov 2004	Dec 2004	Year Total	Forecast Total	
Kaletra-d4T Capsules #34F [KALET-9980-QW1]	1600	1600	1700	1700	1800	1800	1950	2000	800	800	800	800	17350	27050	edit
Blinded Heptanavir/Placebo 200mg Capsules [HEPTAN-AP-6558]	3200	3200	3400	3400	3600	3600	3900	4000	1600	1600	1600	1600	34700	44800	edit
Viral Load Kits [BDNA-VLK-1]	5	5	5	8	8	10	10	10	8	8	8	6	91	112	edit
Case Report Forms [CRF]	100	100	50	10	0	0	0	0	0	0	0	0	260	260	edit

IMPACT® CTMS

Dispatches can be delayed if, for example, the trial, trial country or trial unit is put on hold, and can be subsequently reinstated if required. Alternatively, they can be canceled and any supplies allocated to the dispatch added back as available stock.

[add supplies items](#)

Reference	Name	Batch Reference	Expiration Date	Dispatch Quantity	Quantity Available	
KALET-9980-QW1	Kaletra-d4T Capsules #34F	4556HGT12009	16-May-2005	400	15600	edit
HEPTAN-AP-6558	Blinded Heptanavir/Placebo 200mg Capsules	2009HG9778	11-Nov-2006	600	14400	edit
BDNA-VLK-1	Viral Load Kits	6770095DC	9-Dec-2006	10	143	edit
CRF	Case Report Forms			10	490	edit

[Top](#)

Returns and destruction of supplies – Accountability of returns, lost items and those sent for destruction can be recorded. For a given batch reference or supplies item, inquiry screens show its location across affiliates and sites.

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.