



RIGHT SOLUTIONS. RIGHT NOW.

Right Now Distribution in Clinical Trials

Case Study

FEBRUARY 2014

Study Background:

The purpose of this case study is to provide a comparative analysis between two identical Phase III studies each with a total enrollment of three hundred patients. Both studies were conducted with identical trial designs, drug administration schedules, clinical technologies, CRO and sites. The studies varied only by persistence of the disease condition (acute or chronic) and the strategy used for drug distribution and packaging. The acute study followed a traditional warehousing approach, while the chronic study leveraged Right Now integrated distribution and an On-Demand packaging

The Company:

Eclipse is a specialized, ISO 9001:2008 registered, clinical technology company focused on providing innovative solutions for drug development. With foundational expertise in technology, eclipse has partnered with industry leaders in supply management, pharmacogenomic testing and next generation sequencing to develop efficiencies in clinical supply logistics and trial design methods. Our Right patient, Right dose, Right now program ensures patients receive precise study placement and personalized drug delivery.



Strategies & Costs:

A traditional warehousing approach to product packaging and distribution generally means packaging a predefined amount of kits to ship to each site on activation and a fixed amount to store in a warehouse for site resupply. This may create significant inventories at a warehouse and reduced unit visibility across the study. Complications arise if sites accrue at a rate other than predicted. Medication kits are usually manufactured/ packaged with a predetermined overage, therefore adding to the trial cost waste and lead times for production.

Cost of the medication kits supplied for both the acute and chronic studies stood at **\$1250.00** per kit, while ancillary supplies amounted to **\$57.00**.

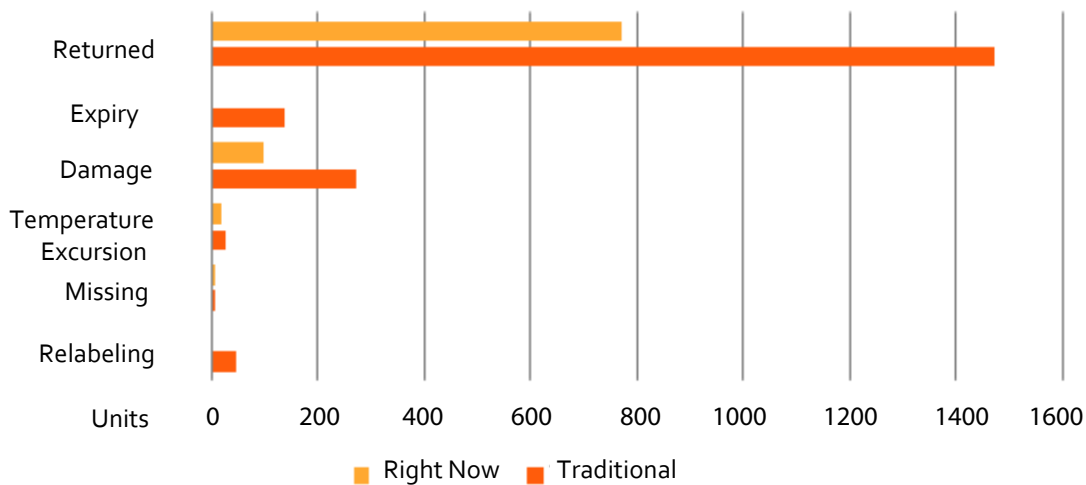
The Right Now integrated distribution model leverages technology driven, on-demand packaging for unbiased selection criteria that enrolls responders and excludes non-responders while accommodating custom dosing for each individual patient based on the genetic and / or metabolic profiles of the patient.

*Right Now
integrated
distribution
reduced
relevant
costs 32%
over the
course of
the trial.*

Relevant Per Study Costs

Description	Unit/Quantity	Acute (Traditional)	Unit/Quantity	Chronic (Right Now)	Savings (%)
Courier Costs	Each / 725	\$135,575	Each / 960	\$150,720	-\$15,145 (-11)
Temptales	Each / 90	\$8,550	Each / 45	\$4,275	\$4,275 (50)
Ancillary Supplies	Kit / 10725	\$611,325	Kit / 7833	\$446,481	\$164,844 (27)
Storage	SqFt / 110	\$93,500	SqFt/ 12	\$10,200	\$83,300 (89)
Returns & Destruction	N/A	\$36,777	N/A	\$8,280	\$28,497 (77)
Monitoring (Routine)	Visits / 369	\$461,250	Visits / 293	\$366,500	\$94,750 (21)
Waste	Kit / 1473	\$1,841,250	Kit / 894	1,117,500	\$723,750 (39)
Monitoring (Reconciliation)	Hours / 256	\$26,880	Hours / 64	\$6,080	\$20,800 (77)
Monitoring (Pass through)	Visits / 369	\$295,200	Visits / 293	\$234,300	\$60,800 (20)
Project/ Drug Management	Months / 36	\$342,000	Months / 36	\$252,000	\$90,000 (26)
Help Desk	Months / 36	\$103,680	Months / 36	\$60,120	\$43,560 (42)
Total		\$3,955,987		\$2,656,456	1,299,531 (32)

WASTE DISTRIBUTION



Key Findings:

The traditional warehousing approach introduced risk to a maximum of **\$1,600,000.00** of warehoused supply for the acute study, while there was nominal inventory for the chronic study.

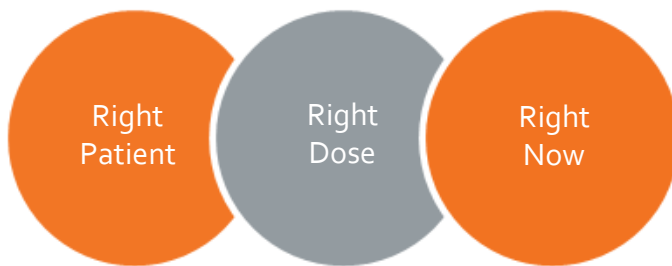
Right Now distribution had a positive impact to all relevant budget line items, with the exception of courier costs. This was due to more frequent shipments. However, per shipment costs were reduced due to smaller shipment containers.

The most significant savings was due to waste, where Right Now distribution resulted in less waste in all areas measured, with 100% savings for waste due to expiry and relabeling.

Right Now distribution reduced all categories of waste, when compared to traditional models.

Conclusion:

Introducing the precision of Right Now integrated drug distribution to clinical trials removes challenges due to logistics for rapid turn-around time on testing and ready access to drug product - while maintaining trial integrity and timelines. Right Now alleviates storage costs related to warehousing medication, lowers risk to product and introduces significant savings for the sponsor.



When combined with the eclipse Right Patient and Right Dose strategies, patients receive maximum benefit through optimal drug dosing. Sponsors and Investigators can provide more targeted care knowing in advance how patients metabolize drugs - minimizing adverse events and maximizing efficacy. And with Right Now integrated distribution, drug is only delivered when and where you need it.

*"Most current supply chains
are entirely inadequate for
the realities of trials today"
(Fleischhacker, 2010)*

RIGHT SOLUTIONS. RIGHT NOW.

42 Hampton Rd • Exeter, NH 03833 **Phone:** 603.294.4580 **Fax:** 866.585.1267
www.eclipsesol.com

Oracle CRO Advantage

ORACLE Silver
Partner