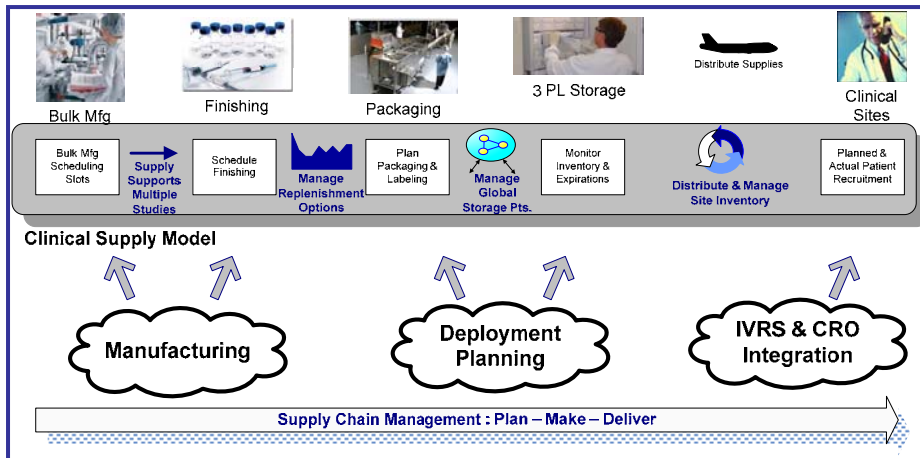


# Clinical Trials Supply Model

## Simulation for Planning Supply of Developmental Products

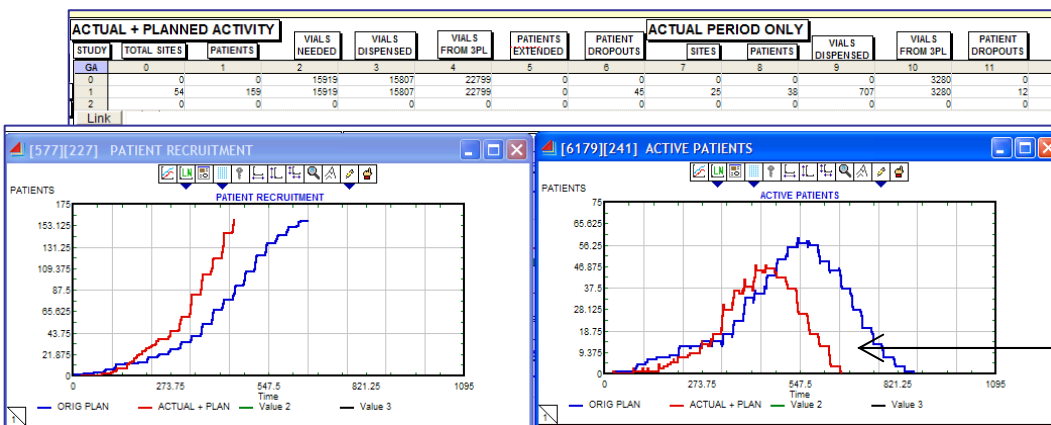
Managing the supply of active and packaged products for clinical trials has been particularly costly in the past due to the complexity of manufacturing and the lack of tools. Using its experience in modeling large scale pharmaceutical manufacturing and supply chains, OpStat has created a tool to manage the supply flow during clinical trials, simulating the impact of timing and scale of operation on resource utilization, product yield and drug substance usage.



All products in trials at any given time may be included in the model, from GMP manufacturing and lab resources through distribution of patient kits. Information on both internal and contract entities' activity may be fed into the model.

### Study Plan & Patient Recruitment

Patient recruitment is a critical input to the process. Before a trial begins, the timing of supply activities is based on the study design and projected ramp-up. Study arms, pack types and visit schedule for each patient are used with the projected recruitment to simulate dispensation from clinical sites back through the supply chain. Actual recruitment and latest projections are included as it proceeds.

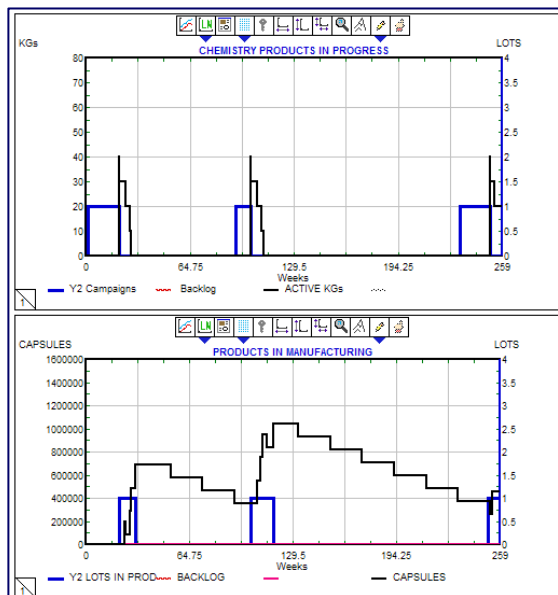


*Predicting an early study completion and a reduction in drug supply needs.*



## Inventory Lot Tracking at Depots & Sites

Based on patient recruitment and inventory replenishment algorithms for clinical sites, the model projects the timing of dispensation, packaging, labeling and production requirements and inventory for bulk API, drug product, packaged product and patient kits. It also tracks actual and projected drug in the pipeline vs. expiration at all depots and clinical sites.

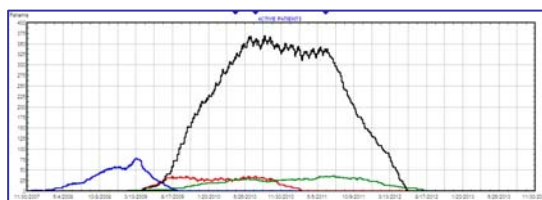


DISPOSAL: DEPOT INVENTORY > EXPIRATION DATE						
Arrival (da)	LOT ID NBR	ExpireDate	Item Nbr	ItemLabelRow	DepotIndex	Demand Amt
4/9/2009	4729	497.75	41000	15	1101	30
5/9/2009	4391	527	31000	9	1103	739
5/9/2009	4391	527	31000	9	1103	300
5/9/2009	4391	527	31003	18	1105	280
10/1/2009	7055	672	91001	7	1101	2200
10/1/2009	7055	672	91001	7	1101	430
10/1/2009	7055	672	91003	18	1101	180
10/1/2009	7055	672	91001	7	1103	410

DISPOSAL: SITE INVENTORY > EXPIRATION DATE					
Arrival (days)	LOT ID NBR	ExpireDate	Item Nbr	SiteIndex	Inv Update
5/24/2009	4392	532	31000	548	8
5/24/2009	4391	527	31000	521	80
5/24/2009	4391	527	31000	521	12
5/24/2009	4391	527	31000	520	80
5/24/2009	4391	527	31003	233	33
5/24/2009	4391	527	31003	232	80
5/24/2009	4391	527	31003	231	80
5/24/2009	4391	527	31003	230	80

## Sites & Patients for Multiple Studies

Patient IDs are assigned at randomization to track actual drug dispensed and to simulate projected treatment. Treatment plans include multiple arms, co-products and adaptive rules.



ACTUAL + PLANNED ACTIVITY						ACTUAL PERIOD ONLY						
STUDY	SITES INITIATED	PATIENTS	VIALS NEEDED	VIALS DISPENSED	VIALS FROM 3PL	PATIENTS EXTENDED	EARLY DEACTV/TNS	SITES	PATIENTS	VIALS DISPENSED	VIALS FROM 3PL	PATIENT DEACTIVATIONS
Ga	0	1	2	3	4	5	6	7	8	9	10	11
0	0	0	0	0	163170	0	0	0	0	0	12590	0
1	51	155	8859	8859	12770	14	141	51	155	5308	11250	83
2	60	122	12312	10280	17820	0	0	6	0	0	460	0
3	33	84	18818	3858	9740	0	0	8	1	48	520	0
4	259	908	187858	107294	143040	0	0	6	0	0	380	0

OpStat Group Inc. has a proven track record with large pharmaceutical companies. Founded in 1986, our staff is expert in operational improvement, and uses simulation tools for analysis of operations. We have adapted our simulation models for use in biotech companies focused on lean operations.



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