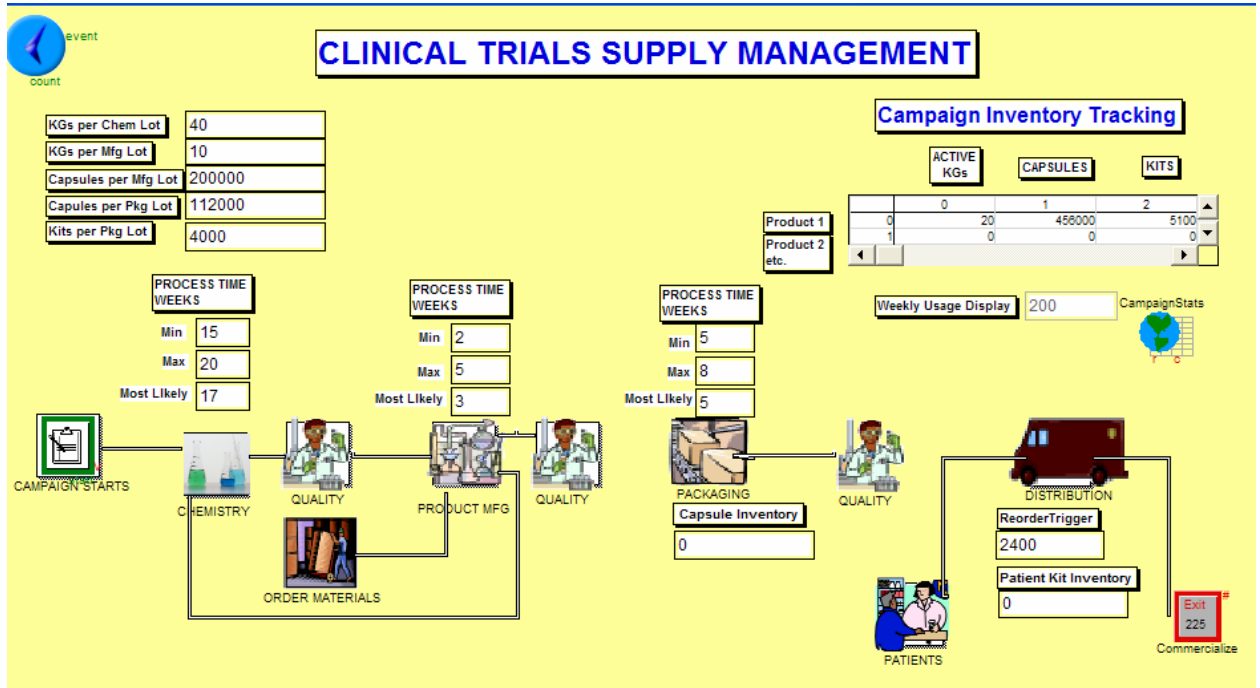


Clinical Trials Supply Model

A New Use of Simulation Technology in the BioScience Industry

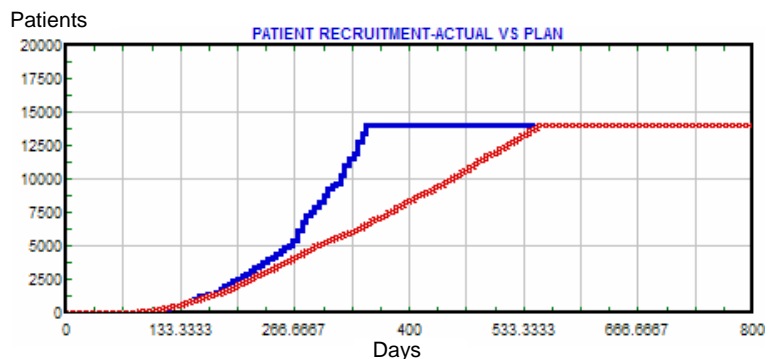
Managing the supply of active and packaged products for clinical trials has been particularly costly in the past due to the complexity of manufacturing and the lack of tools. Using its experience in modeling large scale pharmaceutical manufacturing and supply chains, OpStat has created a tool to manage 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 internal and contract entities' activity may be fed into the model.

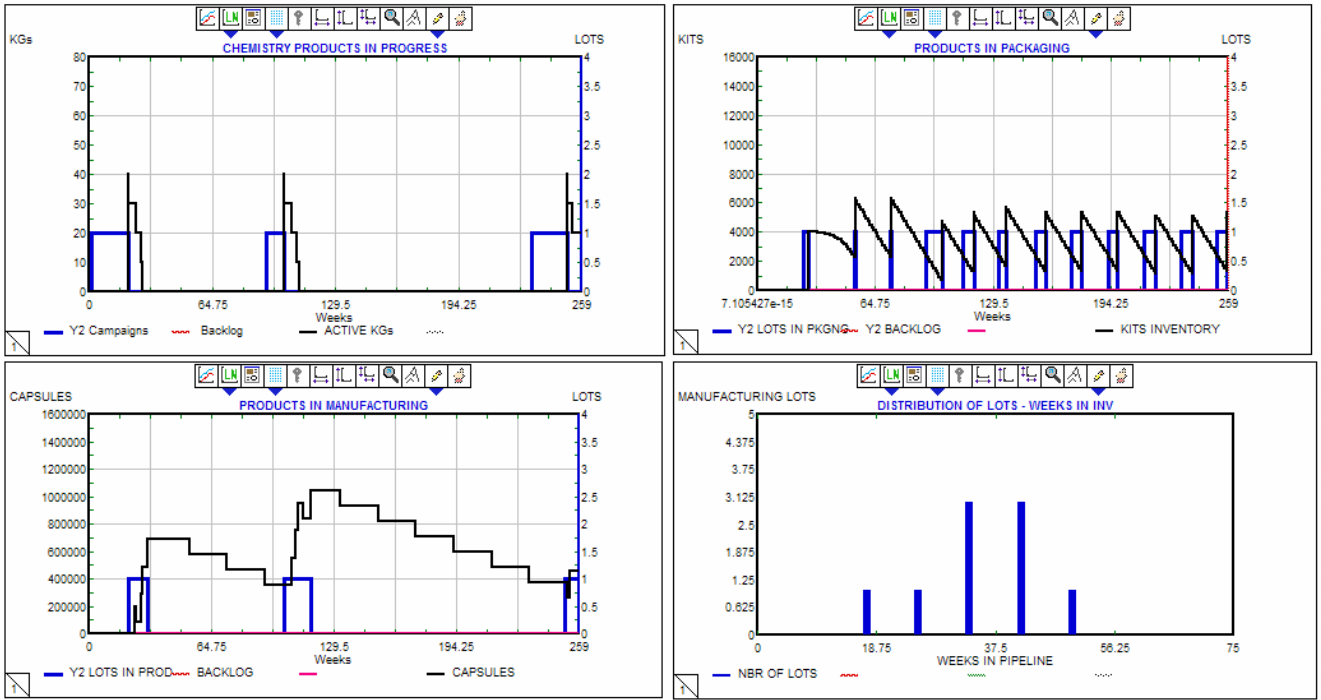
Patient Recruitment

Patient recruitment is a critical input to the process. Before a trial begins, the timing of supply activities is based on the projected ramp-up. Actual recruitment and latest projections are included as it proceeds.



Inventory Tracking

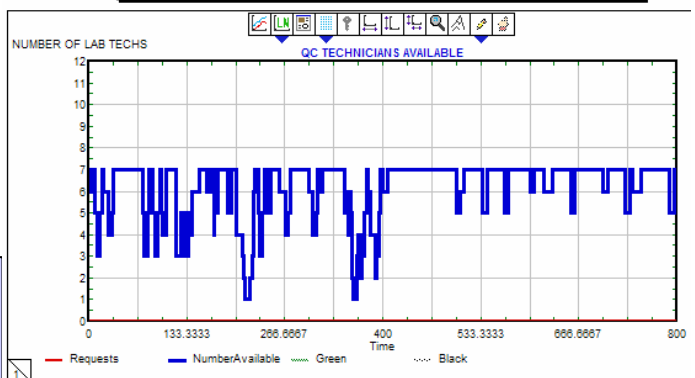
Based on patient recruitment, the model projects the timing of production requirements and inventory for drug substance, drug product, packaged product and patient kits. It also tracks the projected time that product will be in the pipeline vs. expiration.



Resource Utilization

The utilization of critical skilled personnel as well as throughput and utilization of individual sets of equipment in each manufacturing operation's is also tracked.

TRACK THE USAGE OF LAB TECHNICIANS AND DOCUMENTATION ANALYSTS



LOTS Completed	LOTS WAITING			EQUIP UTILIZATION		
	NBR	DAYS		IN USE	CLEANOUT	DOWN
121	4.576	3.471	1	0.43925	0.31153	0.17267
76	3.886	4.661	2	0.41077	0.14419	0.09346
66	4.236	6.009	3	0.58745	0.12283	0.02136

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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