Site Forecasting
Enabled by Confidence Dials

Knowledge Sharing Series

Study Maintenance **Managing Protocol Amendments, System**

Informing Forecasting and Resupply Decisions Based on Business Needs Rather than Complex Calculations

In an ideal world, there would be exactly enough drug at each clinical site around the globe to ensure the study runs smoothly. No wasted supply and no risk of trial disruption Unfortunately, this is not an ideal world but rather the real world of increasingly complex clinical trials.

Supply managers are responsible for ensuring patients are supplied on time and in full. The RTSM plays an integral role in that by requesting the right medication at the right time in the right quantity, from depot to the site.

Site Forecasting

Traditionally, buffer levels (re-supply triggers) are static and are typically defined manually during the specification process. Values are input (into whatever tool you are using) and you hope for the best. This does not account for unexpected or unknown demand or current enrollment rates, but rather based on expected enrollment. This presents challenges to supply managers to achieve accurate forecasts and leads to wasted supply from overly conservative forecasts.

> " *The RTSM plays an integral role in that by requesting the right medication at the right time, in the right quantity, from depot to the site.* "

Forecasting & Re-Supply

This is no longer the case. 4G Clinical's clinical supply forecasting functionality takes the manual work out of site forecasting. The system calculates the total demand for sites and depots by combining buffer levels, enabled by dials, with dynamically updated demand for existing patients.

The system displays the demand for each site so you have complete transparency. Also, the trigger level per site is clear, so you know that when a site's current available inventory falls below that number of kits, a shipment request will be triggered. And you can control the size and frequency of shipments per enrollment group using the long window, again with visibility per site so you can see exactly how big the site's next shipment will be.

	CHALLENGES	SOLUTIONS
BUFFER	Buffer levels (trigger) are static and need to be defined manually	Buffer levels are automatically calculated – for sites and depots – and dynamically adapt to demand
FEEDBACK	No feedback from the system or scenario planning capabilities – black box	Scenario planning with dials and instant feedback. Actual values are only committed when assessed
RE-SUPPLY	Little help with depot re-supply which is often done manually or in separate systems	Automatic, dynamic re-supply is extended to depot level
TEAM	Sometimes missing vendor expertise on re-supply	Expert team, full transparency

Here is how it works:

Buffer Levels for Unknown Patients

This is the greatest variable. You don't know how many or where patients will enroll, so you need to balance your supply constraints (available drug, expense) against your assumed demand (random bursts of enrollment, steady enrollment, or a trickle). The confidence dial allows you to find that balance, and see the resulting buffer levels at your sites.

You choose the level of confidence (%) that the system will account for every possible scenario during your study to avoid stock-out (i.e. 97% of outcomes are accounted for in the calculations). You receive immediate feedback on your supply levels and potential risk.

97%

95 97
90 98
85 99

Confidence over site buffer levels (trigger)
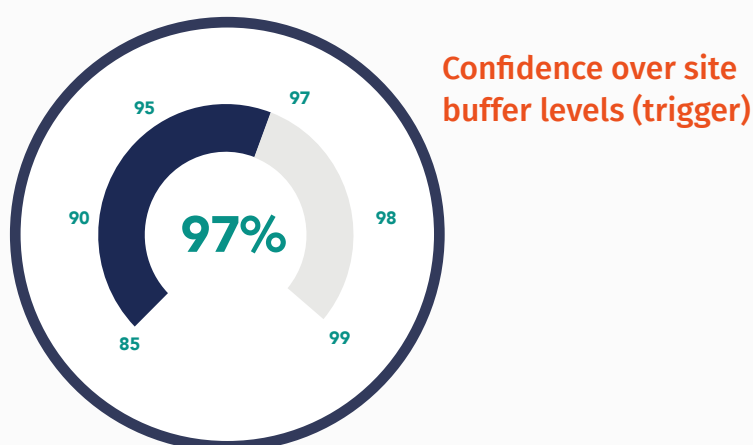
You then have the control to adjust the settings by choosing various confidence levels (with the turn of a dial) and immediately see the impact of supply decisions on buffer levels, shipping size/storage capacity, etc. Only when you are comfortable with the values, you commit to the settings.

Here is how it works:

Together with the buffer for unknown patients, the system accounts for these demand elements:

- **Fully predictable demand (PD – Industry Standard)** – Randomised patients with known demand (most common demand element used in forecasts today).

- **Unpredictable demand (UD – 4G Innovation)**
  a. From active patients (CUD) – Dispensing schedule can vary, for example patient is in screening
  b. From new patients (UUD) – Patients not yet registered in the study, based on enrollment rate

Buffer levels are computed daily based on the forecasted demand and chosen confidence level (instead of fixed buffers).
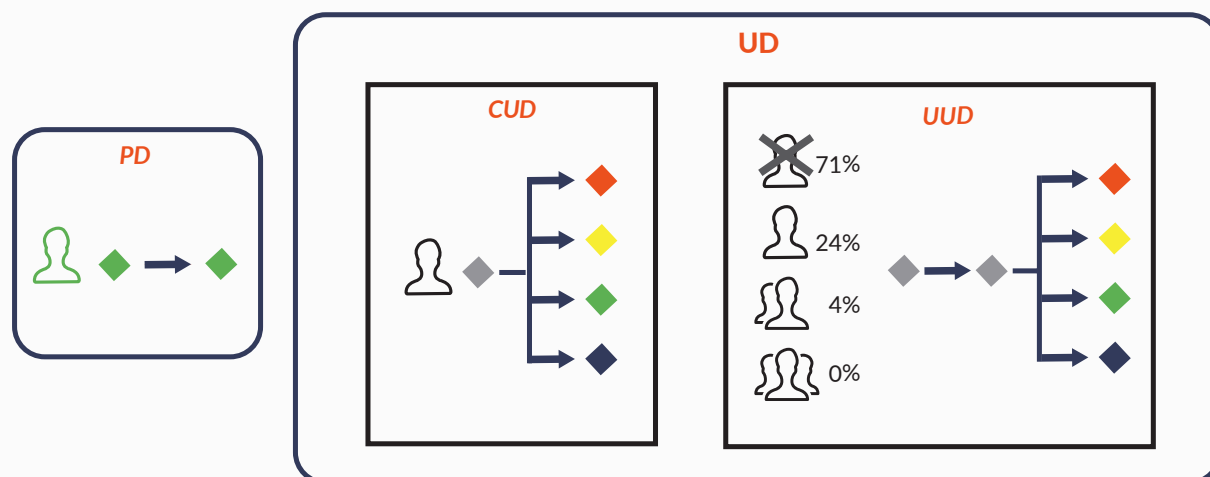
PD = Fully Predictable Demand (Industry Standard)

UD = Unpredictable Demand (4G Innovation)

What Inputs (values) does the System use for **Site Forecasting?**

To calculate trigger levels, you need to input two critical values into the system.

- **Enrollment** – How many patients per site per month are expected
  - Separated out in Enrollment Groups, e.g. Low, Med, High. The supply manager can add/ change them directly in the system.

- **Short Window** – Lead time (How long it takes to get shipment to the site?) + some buffer

The system automatically calculates the demand in both Short Window (SW) and Long Window (LW), giving the supply manager transparency into both site trigger levels as well as shipping size and cadence throughout the study.

Short Window – Site Buffer Levels

The system automatically calculates the Short Window (SW) Demand. The SW accounts for the three levels of demand mentioned above as well as the confidence level set on the dials, and is generally slightly longer than the lead time to ensure security against stock-out.

Inventory Management

Running forecast ——— Last forecast executed on 29-Oct-2018 03:59 PM

Confidence over site buffer levels (partially known and unknown subjects)

97% (90 — 95 — 97 — 80 — 99)

Set/update enrollment groups | RUN INVENTORY CALCULATION | APPLY ALL INVENTORY PARAMETERS | ☐ Expert mode

Enrollment group	pts/m/s	LT	SW	LW	# Sites	Unpredictable demand in Short Window		
						Kitomab (100mg)	Kitomab OL	Placebo
Med	1	7	8	56	6	2	0	2
High	2	7	8	56	1	4	0	4
		7	15	56	1	4	0	4
Low	0.5	7	8	56	2	2	0	2
		7	15	56	1	2	0	2
TOTAL					11	26	0	26

What inputs (values) does the system use for **Site Forecasting?**

Long Window – Days, Site Shipment Cadence

The long window dial is critical to finding the balance between sending small frequent shipments (upcoming expiry dates, limited storage space at sites) or sending larger shipments that will satisfy demand for longer (expensive cold chain shipments, upcoming holidays). You can see exactly what the size of the next shipment will be based on the selected Long Window.

The supply manager can use the short window to ensure sufficient inventory coverage at sites, by setting it to the maximum shipping lead time or a little above. The long window is used to define the shipping frequency and with this the size of shipments.
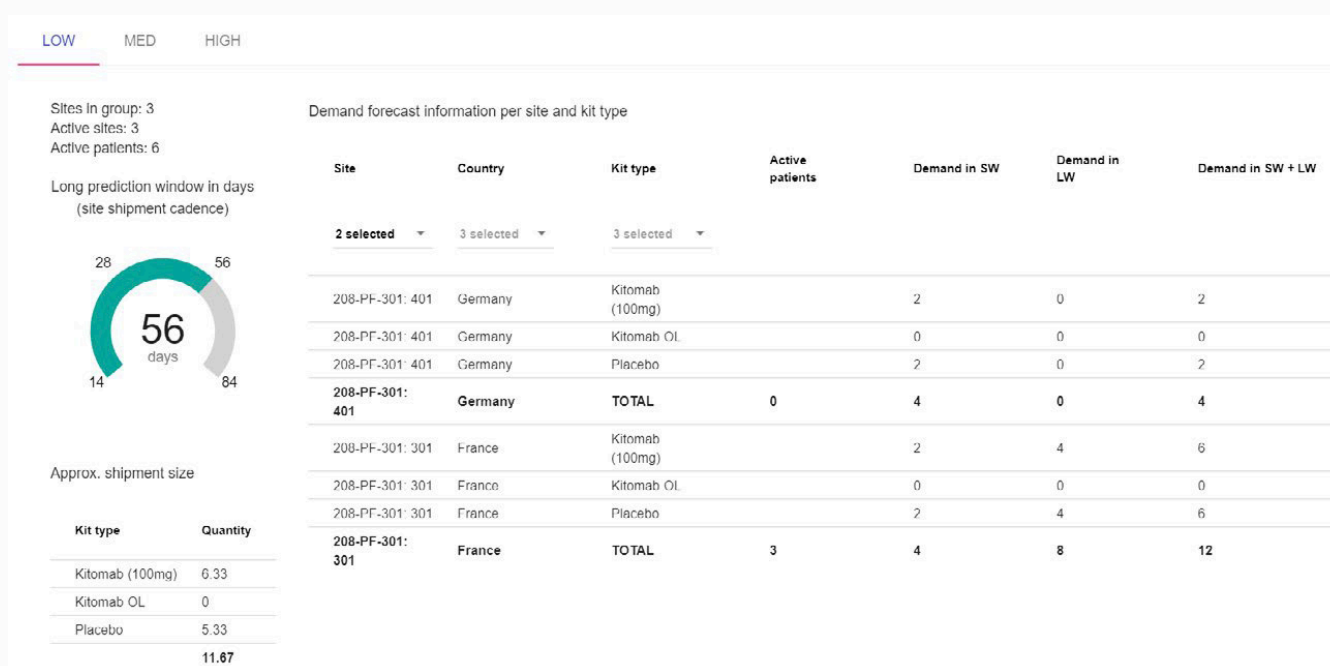
Summary

Most **forecasting tools** today account for **current demand of existing patients**, but not unpredictableor partially known demand.

With 4G's system, the system **automatically calculates unpredictable demand** (generating a trigger level) and the system reacts to patients in screening, accounts for patients that may have upcoming titrations and accounts for known patients that don't have a defined dose.

Results

The supply manager has full transparency at the site level and control over what trigger levels are used. They don't have to rely on understanding the complex calculations but rather make decisions based on scenario planning and business needs.

Meet the **Authors**

Pirmin Froehlicher, Director, Client Services at 4G Clinical, has 6 years of experience in clinical supply and extensive knowledge in clinical supply forecasting and optimisation using CT-Fast and SAP. Pirmin has sound knowledge of RTSM technologies and lead part of a RTSM-SAP integration at a major pharmaceutical company in Switzerland. He believes that, no matter how much you know, there is always more to learn - and it's great to learn from each other. Pirmin holds a BS in Industrial Engineering and a certification asLean Six Sigma Green Belt. He's passionate about processes as well as systems that are efficient, user friendly, and make sense.

Kathleen Greenough Director of Client Solutions at 4G Clinical, has 16 years of experience in life sciences spanning Clinical Operations, Finance, and IT. Her wide range of solutions implementation expertise includes RTSM, CTMS, trial costing tools, OLAP financial suites and patient enrollment planning. Kathleen has also spent many years as a Clinical Financial Planner and Analyst at a major biotech in Cambridge, MA, gaining a broad and deep understanding of the challenges inherent in Clinical Development. Specialising in software adoption and a frequent speaker at industry conferences, Kathleen is most in her element when working within a user community to facilitate solutions that are insightful and truly helpful.

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Still have questions?
Contact us today to start a conversation.

About
4G Clinical

4G Clinical is a leader in randomisation and trial supply management (RTSM) for the global life sciences industry, offering the only fully cloud-based, 100% configurable and flexible solution utilising natural language processing (NLP) and integrated supply forecasting.

Our expert staff possesses a combination of humility, confidence, curiosity and commitment to getting things done. Most importantly, everyone at 4G Clinical is passionate about our mission of bringing crucial medicines to those who need them, faster.

4G Clinical is a global leader in randomisation and trial supply management (RTSM) for the life sciences industry, offering the only fully cloud-based, 100% configurable, and flexible solution utilising natural language processing to accelerate clinical trials. 4G Clinical is headquartered in the U.S., with offices in Wellesley, Massachusetts, Portland, Oregon and Raleigh, NC. The company also maintains nine additional locations worldwide, with offices in Tokyo, Amsterdam, Copenhagen, Dublin, Brussels, Tel Aviv, Basel, Nottingham, and Rheinbach. To find out more about 4G Clinical's expertise and advisory services to bio/pharmaceutical companies and contract research organisations, visit **www.4gclinical.eu**

About 4G's Clinical Supply Forecasting

Supply planners no longer have to build excel sheets or have the knowledge base to decode complex algorithms to inform supply decisions.

4G's clinical supply forecasting solution enables you to make decisions based on business need rather than relying on complex calculations. As the world's first integrated RTSM and clinical supply forecasting solution, supply planners employ real-time visibility and leverage scenario planning to control supply decisions.