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Clinical Supply Forecasting Software Comparison 2026

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Executive Summary

Clinical supply forecasting software is not one product category. It is a stack of four decisions: how much demand to expect, how uncertain that demand is, which supply policy to buy against it, and how the policy is executed in randomization and trial supply management (RTSM) software. This report compares **Signant Health**, **N-SIDE**, **SAP Intelligent Clinical Supply Management (ICSM)** and **Bluefin** on those layers, and adds **STAEDEAN** and RTSM-embedded modules for context. All product descriptions are vendor statements unless an independent source is named. We did not identify an independent head-to-head benchmark of these products as of 29 October 2026.

The clearest methodological split is documented by N-SIDE: forecasting tools take overage as an input, while risk-based optimization tools produce it as an output ((www.n-side.com)). SAP documents deterministic demand calculation with scenario simulation ((www.sap.com))((www.sap.com)). Signant describes simulation models and scenario planning without naming a method ((signanthealth.com)). Bluefin describes plans as "mathematically optimized" without publishing the algorithm. Publicly documented method detail therefore differs sharply by vendor, and it is a procurement question, not a ranking.

Ownership and roadmap changed recently. **Endpoint Clinical L.P.** announced the acquisition of Bluefin on **14 September 2026** ((bluefin.one)), and Endpoint's newsroom says Bluefin will operate independently and keep connecting to RTSM systems across the industry ((www.endpointclinical.com)). Signant announced a four-agent **Forecasting and Planning Assist** bundle on **3 August 2026** ((signanthealth.com)).

The quantitative claims in the market are large and unreconciled. Vendors state waste or cost reductions between 2% and 60% ((www.sap.com))((www.medidata.com)), none with a baseline in the pages reviewed. The oldest traceable survey-style figure among the vendor-era claims is a 2017 vendor-authored review in which **62%** of packaged and released material across 200 studies went unused ((www.appliedclinicaltrialsonline.com)).

To make the comparison testable, this report builds an editable reference trial (300 participants, 30 sites, three countries; a hypothetical example). Expected demand is **2,739 kits** in the base case. A pooled 95% trial-level buffer adds **65 kits** (2.4%), while unpooled site-level safety stock adds **182 kits** (6.6%), and a slow-enrollment scenario exposes **251 kits** (9.2%) to a shelf-life cutoff. Buyers should replay such a case through each vendor, require exported assumptions, and map the handoff to RTSM, ERP and depot systems against validation expectations such as **ICH E6(R3)** interface definition ((database.ich.org)).

Introduction and Background

Clinical supply planners decide how many kits of investigational product to manufacture, package, label and place across depots and sites before and during a trial. Overbuying wastes expensive drug; underbuying risks missed dispensing. A 2019 Winter Simulation Conference tutorial notes that drug supply planning has long relied on largely deterministic calculations using averages ((www.informs-sim.org)), and that pre-trial estimates of site enrollment rates tend to be inaccurate ((www.informs-sim.org)). Enrollment shortfalls are common: an analysis of closed cardiovascular trials on ClinicalTrials.gov found poor accrual was the most common reason for non-completion (41%) ((bmjopen.bmj.com)), and a review of 12,875 oncology trials identified poor accrual as the main cause of early termination ((pubmed.ncbi.nlm.nih.gov)).

This report compares software that sits before and beside execution. It excludes randomization engines and general commercial supply chains. It also does not treat "AI" labels as evidence; the test applied throughout is whether a vendor documents assumptions, constraints and reproducible outputs.

Five layers, defined

- **Forecast:** a deterministic estimate of expected demand. N-SIDE describes forecasting tools as aiming to predict patient demand in a trial ((www.n-side.com)), and **Perceptive (Calyx)** defines a forecast as a static prediction or estimate ((www.perceptive.com)).
- **Stochastic simulation:** repeated runs over uncertain inputs. N-SIDE says such tools can predict more than average demand after thousands of simulations ((www.n-side.com)). A pure simulation model takes the inventory policy as an input and reports service performance ((www.informs-sim.org)).
- **Optimization:** a search for the policy itself. N-SIDE says optimization also sets IRT parameters such as safety stocks, trigger levels and resupply frequency ((www.n-side.com)). Not all risk-based tools are Monte Carlo: a GSK statistician described a tool that used closed-form expressions and no Monte Carlo simulation ((www.pharmoutsourcing.com)).
- **Planning:** conversion of demand into manufacturing, packaging and shipment plans, for example the planning and forecasting module in SAP's four-module structure described below.
- **Execution (RTSM or IRT):** systems that, in one trade-press description, execute randomization, blinded supply and resupply management to depots and sites ((www.appliedclinicaltrials.com)).

System boundaries and why they matter

A recurring integration risk is a forecast that is detached from the resupply algorithm actually running in the IRT. A 2017 vendor perspective stated that many sponsors use forecasting systems detached from the actual IRT ((www.appliedclinicaltrials.com)), and the 2019 tutorial identified a disconnect between enrollment

forecasting and supply planning ((www.informs-sim.org)). Regulators treat the boundary as a documentation topic: ICH E6(R3) expects sponsors to keep a record of important computerised systems ((database.ich.org)) and to define interfaces between systems ((database.ich.org)), while **EU GMP Annex 11** expects data flows and interfaces to be described for critical systems ((health.ec.europa.eu)).

Evidence base and perspective

The research behind this report opened vendor pages, product documentation, press releases, peer-reviewed papers and regulator texts between 19 September and 29 October 2026. Product pages are first-party claims, not proof of performance, compliance or return on investment. Where a capability is not documented in the pages reviewed, this report says so and does not infer a weakness. We did not identify a neutral head-to-head comparison of these products among the public sources reviewed.

IntuitionLabs is a life-sciences and AI consultancy and a Veeva X-Pages Partner. Veeva appears in this comparison in the RTSM-embedded forecasting section, where its published resupply brief is cited; that relationship did not influence which vendors were compared or how they were described. IntuitionLabs does not sell any product compared here, and its perspective is limited to the selection and governance guidance in this text.

Signant Health: SmartSignals Supplies Forecasting and Planning

Capabilities

Signant places forecasting and planning in its SmartSignals Supplies suite, next to GxP Inventory, which the company says integrates with RTSM and IRT systems ((signanthealth.com)). The product page describes a monthly rhythm: recruitment is reviewed and revised monthly before demand updates automatically ((signanthealth.com)), and stock is allocated monthly to support reservation and pooling ((signanthealth.com)). It states that the software graphs supply and demand before suggesting manufacturing plans ((signanthealth.com)).

The brochure refers to simulation models and scenario planning ((signanthealth.com))((signanthealth.com)) and lists optimally timed mid-study production runs as a benefit. A company blog states that automatic Bill of Materials aggregation covers demand across trials ((signanthealth.com)) and that comparators, co-medications, ancillaries and devices are handled ((signanthealth.com)). The pages reviewed do not state the simulation method, confidence levels or how scenarios are versioned.

In August 2026 Signant launched Forecasting and Planning Assist, licensed as four agents in one bundle ((signanthealth.com)). Documented agent tasks include updating enrollment actuals and modeling recruitment scenarios ((signanthealth.com)), flagging lot expiries, lead-time risk and stockout exposure ((signanthealth.com)), and configuring depot networks ((signanthealth.com)). Signant says a GxP-compliant audit trail is maintained ((signanthealth.com)) and that the agents operate only within verified data structures ((signanthealth.com)). Notably, the Assist pages frame outputs as flags, not automated resupply orders.

Adoption and Evidence

Signant states its RTSM has implemented more than **2000 protocols in 90 countries** ((signanthealth.com)); that figure describes RTSM, not the forecasting module. An anonymized October 2025 case study quotes a biotech customer on live, daily imported IRT data ((signanthealth.com)). The suite is cloud hosted on AWS ((signanthealth.com)), and a label-printing integration with Lofware reached general availability for GxP Inventory in November 2024 ((whattheythink.com)). The RTSM exposes APIs with near real-time data access for integrations ((signanthealth.com)).

Savings claims are vendor-stated: the product page headline says "Save over 20% on your annual budget" ((signanthealth.com)), and the brochure adds a minimum-savings statement and a waste-reduction claim summarized in *Table 3* (see Data Analysis and Evidence). The pages reviewed give no baseline, sample size or study design for these figures.

Strengths and Limitations

- **Documented strengths:** one vendor spans forecasting, GxP inventory and RTSM, and the Assist release adds expiry and stockout flags with an audit trail statement.
- **Documented context:** the product page lists protocol amendments, undefined doses and unexpected recruitment rates as the disruptions it addresses ((signanthealth.com)).
- **Not documented in the pages reviewed:** simulation method, scenario version control, approval workflow, planner override mechanics and a direct ERP connector for the forecasting module. These are diligence questions, not findings of absence.

N-SIDE: Supply App, Lighthouse and Risk-Based Optimization

Capabilities

N-SIDE separates a standardized tier (Lighthouse) from a high-stakes tier (Supply App). Lighthouse is described as modeling trials in minutes and simulating multiple scenarios ((www.n-side.com)). The Supply App simulates a trial from first patient in to last patient last visit, including packaging and dispensation ((www.n-side.com)).

N-SIDE's own insight article, cited in the Introduction, is the clearest public statement of the forecast-versus-optimization distinction: overage as an output, simulation ranges instead of averages, and IRT parameter setting. A companion article lists drug shelf life and expiry replacements among modeled factors ((www.n-side.com)) and says a tool should provide minimum and maximum demand boundaries ((www.n-side.com)). The Supply App page says users can quantify trade-offs across service level, inventory, timelines, waste and budget ((www.n-side.com)) and see how changes in recruitment, dropout or delays affect the plan ((www.n-side.com)).

Adoption and Evidence

N-SIDE reports that **70% of the top 20 pharmaceutical companies** use its solutions, in its own 2025 results ((www.n-side.com)). A 2023 release stated that over 700 active trials were managed with its solutions ((www.pharmavoice.com)). Integration with **Suvoda** is the best-documented RTSM link: a 2022 release says

Suvoda's IRT implements optimized resupply strategies through adapted IRT algorithms ((suvoda.com)), and that the companies had partnered on more than 100 trials ((suvoda.com)). Suvoda states that a direct link delivers real-time IRT data to N-SIDE ((www.suvoda.com)), without describing transport or latency in the page reviewed. An **Almac** and N-SIDE trade article describes nightly incremental forecast updates ((www.worldpharmaceuticals.net)) and periodic human review with re-simulation when warranted ((www.worldpharmaceuticals.net)), which is a useful governance reference.

N-SIDE's quantified claims vary by page. One page states 20-50% overall cost savings and 20-60% drug waste reduction, while a 2023 release says waste in large trials falls from 70% to 25% on average ((www.pharmavoice.com)). Both appear in *Table 3* (see Data Analysis and Evidence); the two statements use different bases and are not reconciled in the pages reviewed.

Strengths and Limitations

- **Documented strengths:** explicit service-level and overage outputs, minimum and maximum demand ranges, and a named IRT partnership ((suvoda.com)).
- **Integration breadth:** the ecosystem page claims integration with IRT/RTSM, inventory tools and ERP systems ((www.n-side.com)), and Lighthouse lists Excel imports and open APIs ((www.n-side.com)).
- **Security:** N-SIDE states ISO 27001 certification ((www.n-side.com)). That is an information-security standard, not GxP validation evidence.
- **Not documented in the pages reviewed:** GxP or **21 CFR Part 11** validation packages, planner override roles, approval workflow and named ERP connectors. The 2019 launch release did describe alerts when studies deviate from agreed uncertainty assumptions ((www.biospace.com)), which helps explainability, but it predates current releases.

SAP Intelligent Clinical Supply Management

Capabilities

SAP's product is documented in four modules, which SAP Learning lists as study management, planning and forecasting, manufacturing and packaging, and distribution ((learning.sap.com)). The product page lists hybrid deployment with cloud and on-premise modules ((www.sap.com)) and integration with clinical trial management (CTMS) and IRT systems ((www.sap.com)). On planning, SAP documents simulation of multiple scenarios from projected or actual enrollment and visits and deterministic calculation for demand planning, as noted above. The November 2025 scope document adds demand scheduling with support for subject switching ((help.sap.com)) and thresholds, alerts and automatic re-planning ((help.sap.com)).

The distribution module is described as verifying that materials reach destinations within valid shelf life ((learning.sap.com)). Governance features are listed in general terms: e-signature, documented approvals and audit trails ((www.sap.com)). A separate add-on, **predictive subject dynamics**, is described as predicting enrollment and dropouts ((www.sap.com)); it requires the base product ((www.sap.com)).

Adoption and Evidence

The product is documented as released in 2022 by a partner source ((www.hcltech.com)). SAP's learning material describes an inbound IRT interface carrying actual enrollment at visit level ((learning.sap.com)) and an outbound API to retrieve demand forecast figures ((learning.sap.com)). The SAP help scope document describes CMO integration through subcontracting purchase orders ((help.sap.com)). An April 2026 SAP event agenda listed a session on ICSM with SAP Integrated Business Planning ((events.sap.com)); that is an agenda title, not product documentation of the link.

Oracle's Clinical One documentation shows what a file-based RTSM-to-SAP handoff looks like: SAP posts a stock report to an sFTP server ((docs.oracle.com)), and the RTSM posts a cumulative enrollment file for forecasting and planning ((docs.oracle.com)). SAP also states a business value for the predictive add-on, summarized in *Table 3* (see Data Analysis and Evidence) without a stated method.

Strengths and Limitations

- **Documented strengths:** coverage across planning, packaging, distribution and the ERP, with approvals and audit trails stated.
- **Licensing:** SAP's scope document notes that restrictions may apply under the customer license agreement ((help.sap.com)). Public pricing was not found; the product page directs buyers to a demo.
- **Not documented in the pages reviewed:** stochastic risk modeling, mathematical optimization of overage and safety stock, and a named validation package. Absence of documentation is not absence of capability; ask SAP directly.

Bluefin and Endpoint

Ownership and contracting

Bluefin's homepage states it is now part of Endpoint ((bluefin.one)). The acquisition announcement names Endpoint Clinical L.P., a randomization and trial supply management company, as acquirer ((bluefin.one)). Endpoint's newsroom states that Bluefin will operate independently and continue to connect with RTSM systems across the industry ((www.endpointclinical.com)). The release describes an open, RTSM- and forecasting-agnostic model ((bluefin.one)), and a stated aim of linking supply plans to trial execution data to anticipate enrollment shifts and automate forecasting ((bluefin.one)). The roadmap statement is directional only: the companies are building a clinical supply intelligence platform ((bluefin.one)), with no dates or deliverables in the document. The release and site pages reviewed do not state which legal entity contracts with customers, which should be confirmed during procurement.

Capabilities

Bluefin markets mathematically optimized planning with no formulas needed ((bluefin.one)) and plans that reduce stockout risk and overage cost ((bluefin.one)). Its public changelog is unusually informative. Release 1.5 introduced supply planning that triggers a re-order at a minimum threshold ((bluefin.one)); release 2.5 allowed overage inputs at study and depot level ((bluefin.one)); release 3.1 added lot recommendations with shelf-life extension, lead time and order-size inputs ((bluefin.one)); release 4.5 added depot-to-depot

shipments (([bluefin.one](#))); and release 5.0 added dosing actuals so that only actuals are used before the reconciliation date and forecasting resumes afterward (([bluefin.one](#))). The changelog also lists scenario cloning and draft lots (([bluefin.one](#))) and a change making participant transitions deterministic to improve scenario reproducibility (([bluefin.one](#))).

That last item matters for explainability. The changelog wording indicates the engine had used random sampling for transitions, and that reproducibility of scenario outputs was treated as a product requirement. It does not describe the optimization method itself.

Adoption and Evidence

Bluefin announced SOC 2 compliance in January 2025 (([bluefin.one](#))), a security attestation distinct from GxP validation. Its platform blog argues that connecting a planning system to an IRT from a different vendor is painful (([bluefin.one](#))), which explains the vendor-agnostic positioning and the later alignment with an RTSM provider. The changelog says release 4.30.0 improves auditability (([bluefin.one](#))) without detail. Customer counts, pricing and independent validation evidence were not found.

Strengths and Limitations

- **Documented strengths:** transparent release notes, depot-level overage inputs, lot and label recommendations, and a stated commitment to stay RTSM-agnostic.
- **Open diligence items:** the optimization algorithm, e-signature and Part 11 position, validation package, and how the Endpoint relationship affects roadmap priorities and contracting.

STAEDEAN and RTSM-Embedded Alternatives

STAEDEAN

STAEDEAN's clinical supply software is embedded in Microsoft Dynamics 365 Finance and Supply Chain Management (([staedean.com](#))). It is closer to an ERP-native inventory and quality layer than to a stochastic planning engine. The page describes predictive insights for demand forecasting (([staedean.com](#))), an end-to-end audit trail with electronic signatures (([staedean.com](#))) and automatic label printing (([staedean.com](#))). A validation toolkit page states the software is **GAMP 5** Category 4 (configurable) (([staedean.com](#))). A factsheet landing page claims 35% fewer inventory overages, with no method given (([staedean.com](#))). No scenario simulation or optimization is documented on the pages reviewed.

RTSM-embedded forecasting

Several RTSM vendors document built-in or partnered planning. **4G Clinical** lists multi-scenario modeling across manufacturing, packaging and distribution (([www.4gclinical.com](#))) and third-party planning integration (([www.4gclinical.com](#))). **Medidata** announced a partnership to bring supply forecasting optimization to Rave RTSM (([www.medidata.com](#))). Veeva's brief says resupply calculations run nightly (([www.veeva.com](#))) with overrides by site or country (([www.veeva.com](#))) and auditable calculation history (([www.veeva.com](#))). Perceptive (Calyx) offers consultant-run simulation using more than 50 design parameters that mimic an IRT

((www.perceptive.com)), and **Clario** lists a trial supply optimization feature inside its IRT ((info.clario.com)). A 4G Clinical patent argues forecasting tools often pull RTSM data by file transfer rather than API ((patents.google.com)), which is the patent's own framing.

Feature Comparison

Table 1 below summarizes documented capabilities across the four main contenders. Cells describe what vendors state in the pages reviewed. "Not documented" means the pages reviewed did not describe the item; it is not a score, a zero or a finding that the capability is missing.

Dimension	Signant Health	N-SIDE	SAP ICSM	Bluefin (Endpoint)
Stated method	Simulation models; method not named in pages reviewed	Repeated simulation of uncertain parameters; outputs are ranges ((www.n-side.com))	Deterministic calculation plus scenario simulation (see SAP section)	"Mathematically optimized"; algorithm not published ((bluefin.one))
Scenarios and versions	Recruitment scenarios in Assist (see Signant section); versioning not documented	Multi-scenario simulation in Lighthouse ((www.n-side.com))	Multiple planning scenarios ((learning.sap.com))	Scenario cloning, draft lots ((bluefin.one))
Uncertainty and service level	Not documented	Min/max demand ranges and service-level trade-offs (see N-SIDE section)	Thresholds and alerts ((help.sap.com))	Stockout risk and overage goal, vendor claim ((bluefin.one))
Enrollment and dropout	Recruitment revised monthly (see Signant section)	Sensitivity to recruitment and dropout ((www.n-side.com))	Subject switching; predictive dropout add-on, extra product ((www.sap.com))	Dosing actuals and reconciliation date ((bluefin.one))
Expiry, packaging, labeling	Lot expiry flags ((signanthealth.com))	Shelf life and expiry replacements ((www.n-side.com))	Shelf-life verification in distribution ((learning.sap.com))	Pack and label lot recommendations ((bluefin.one))
Depot and resupply	Depot network configuration ((signanthealth.com))	Simulation through packaging to dispensation ((www.n-side.com))	Distribution module (see SAP section)	Re-order triggers ((bluefin.one)); depot transfers ((bluefin.one))
Overrides, approvals, audit	Audit trail for Assist agents ((signanthealth.com))	Not documented in pages reviewed (ISO 27001 only)	E-signature, approvals, audit trails stated (see SAP section)	"Improves auditability" ((bluefin.one))
RTSM and ERP links	RTSM/IRT via GxP Inventory ((signanthealth.com))	IRT/RTSM, inventory, ERP ((www.n-side.com))	IRT enrollment inbound, forecast API outbound ((learning.sap.com))	RTSM-agnostic stated ((www.endpointclinical.com))

Three patterns stand out. First, only N-SIDE and, by implication, Bluefin describe risk or overage as a computed output, and both leave method detail to demos. Second, SAP and Signant document governance (approvals, audit trails) more explicitly than their method. Third, every vendor's integration statement is a

capability claim; none of the pages reviewed publish latency, field-level mappings or error handling, so these must be tested.

Performance and Benchmarks

We did not identify a public benchmark comparing these products on forecast accuracy, stockout rates or waste. The oldest relevant non-vendor evidence we found is simulation research. A 2004 simulation study reported, in one modeled example, that a traditional supply approach produced 75% overage ((pubmed.ncbi.nlm.nih.gov)) and that, in repeat-dispensing designs, predictive algorithms can cut packs required by up to 50% ((pubmed.ncbi.nlm.nih.gov)). A GSK statistician reported that modeled overage rises steeply when accepted stockout risk falls below 5% ((www.pharmoutsourcing.com)) and that stockout risk cannot be removed entirely ((www.pharmoutsourcing.com)). A 2023 preprint proposes simulation plus optimization for pre-study supply strategy ((arxiv.org)). These support the logic of risk-based sizing, not the performance of any listed product.

Reference Trial (Hypothetical Example)

The following editorial calculation was run on 29 October 2026 as a transparent baseline. All figures are kits (units), for a hypothetical trial with no real-world geography beyond the three illustrative countries. Inputs: 300 randomized participants; 30 sites (15 in the United States, 9 in Germany, 6 in Japan); six dispensing visits at 28-day intervals; kits per visit 1, 1, 2, 2, 2, 2 (titration up at week 8); cumulative dropout by the last visit 15% (base), linear across visits; first patient in 60 days after lot release; 24-month shelf life with a 90-day minimum remaining shelf life at dispensing; central buffer at a 95% trial-level service target ($z = 1.645$); site stock sized for a 42-day window (28-day visit interval plus 14 days lead time).

Method: expected kits per participant = sum over last-visit probabilities of cumulative kits dispensed (**9.130** in the base case); expected demand = 300 times that. The trial-level buffer is 1.645 times the standard deviation of total demand (independent participants). Site safety stock approximates demand in a 42-day window per site as a compound Poisson process and sums sites without pooling. Expiry exposure is expected demand dispensed after day 640 (730 minus 90). A Monte Carlo cross-check of 300 runs gave a mean demand of 2,739 kits and 251 kits after the cutoff in the slow scenario, which the author reports as consistent with the closed forms. The script is not published and 300 runs is a small sample for tail exposure, so treat the site-level safety stock and expiry exposure figures as indicative.

Table 2 below reports three scenarios.

Scenario	Enrollment period	Cumulative dropout	Expected demand (kits)	Pooled 95% buffer (kits, % of demand)	Unpooled site safety stock (kits, %)	Shelf-life exposure (kits, %)
A. Base	12 months	15%	2,739	65 (2.4%)	182 (6.6%)	0 (0.0%)
B. Slow enrollment	18 months	15%	2,739	65 (2.4%)	156 (5.7%)	251 (9.2%)
C. Fast, high dropout	9 months	30%	2,478	86 (3.5%)	190 (7.7%)	0 (0.0%)

Interpretation: demand changes little with enrollment speed but strongly with dropout, while expiry risk appears only when enrollment stretches past the shelf-life window. The pooled buffer is a lower bound, because it assumes instant redistribution across sites. The unpooled figure is a conservative bound, because it assumes no redistribution. For comparison, a flat 20% rule-of-thumb overage would add 548 kits in scenario A. A real planner would also add comparator supply, ancillary items and country-specific labeling lots, which this baseline excludes.

Using the baseline to test vendors

Ask each vendor to load the same inputs and return: expected demand, a distribution or range, the buffer or overage it recommends and the service level it assumes, the resupply parameters passed to IRT, and the expiry exposure in scenario B. Differences from Table 2 are not errors by themselves; the test is whether the vendor can show its assumptions, constraints and seed or version so that the output can be reproduced. The FDA expects validation of electronic systems in clinical investigations to cover configurations, customizations, data transfers and interfaces between systems (www.fda.gov).

Integration, Governance and Validation

Data flows to define

Map five flows before selecting software: enrollment and visit actuals from RTSM to planner; recommended resupply parameters from planner back to RTSM; lot, expiry and release status from ERP or inventory system; depot shipments and receipts; and approved plan exports for manufacturing and packaging orders. Documented examples are file-based and API-based. Oracle's SAP integration uses sFTP files in both directions (docs.oracle.com)(docs.oracle.com), SAP documents inbound IRT and outbound forecast APIs (learning.sap.com)(learning.sap.com), and Medidata describes a pre-validated two-way integration with large depot vendors (medidata.com). Update cadence is therefore a design choice: nightly in the Almac and Veeva documents cited above and monthly in Signant's recruitment review.

Governance pattern for forecast refresh and approval

1. **Baseline:** freeze the approved assumptions (enrollment, dropout, titration, visit windows, shelf life) as a numbered version.
2. **Refresh trigger:** refresh on schedule and on thresholds, for example when actual enrollment deviates beyond a defined band, as Signant's Assist brochure describes for enrollment alerts (signanthealth.com) and as N-SIDE's 2019 release described for uncertainty deviations (www.biospace.com).
3. **Review, then simulate:** a named planner reviews trends and re-simulates only when warranted, as in the Almac and N-SIDE workflow (www.worldpharmaceuticals.net).
4. **Approve:** a second role approves changes that alter manufacturing, packaging or IRT parameters, with electronic signatures where the tool supports them (staedean.com).
5. **Override log:** record who overrode which parameter and why. Veeva's brief, cited above, shows the type of granular override and calculation history that is worth requiring.

6. **Reconcile:** compare plan, IRT settings and ERP stock monthly, consistent with the quantity reconciliations expected in EU GMP **Annex 13** ((health.ec.europa.eu)).

Validation expectations

Planning tools that influence investigational product supply fall under computerised system expectations. 21 CFR Part 11 requires validation of systems to ensure accuracy, reliability and consistent intended performance ((www.ecfr.gov)) and secure, time-stamped audit trails ((www.ecfr.gov)). ICH E6(R3) points to risk-based validation ((database.ich.org)), and FDA says the approach should be proportionate to risks to participant safety and result reliability ((www.fda.gov)). EU GMP Annex 11 expects applications to be validated and infrastructure qualified ((health.ec.europa.eu)). ISPE's GAMP 5 second edition emphasizes the role of suppliers, which matters for software-as-a-service tools ((ispe.org)). Labeling rules also shape planning inputs: the EU Clinical Trials Regulation requires expiry or re-test date in month and year format on labels ((www.legislation.gov.uk)). This report is not legal or regulatory advice; consult qualified quality and regulatory professionals for your jurisdiction.

Data Analysis and Evidence

Table 3 collects the quantitative claims encountered, with their stated origin. All vendor rows are marketing claims; the one row not taken from a product page (Cenduit) is older and vendor-authored.

Source	Claim (unit, date)	Basis stated
Signant	At least 20% of annual supply budgets saved ((signanthealth.com)); waste cut by up to 30% ((signanthealth.com))	No baseline or sample in pages reviewed
N-SIDE	20-60% drug waste reduction and 20-50% cost savings ((www.n-side.com)); 70% to 25% waste in large trials, 2023 ((www.pharmavoice.com))	Vendor-reported, bases differ
SAP	2% reduction in clinical inventory waste costs for the predictive add-on ((www.sap.com))	No method on page
STAEDean	35% lower inventory overages ((staedean.com))	No method on page
Medidata	Supply cost reduction of more than 30-60%, 2022 ((www.medidata.com))	Executive statement in a release
Cenduit review	62% of packaged material unused across 200 studies, 2017 ((www.appliedclinicaltrials.com))	Vendor-authored; underlying report not located

The spread (2% to 60%) cannot be averaged or ranked: baselines, trial types and definitions of waste differ, and none is independently audited. The figure with the most traceable provenance is the 62% unused material, but its originator is an IRT vendor and the study set was prior to 2017. The Rutgers dissertation on drug supply states only that supply costs frequently account for a significant portion of pharmaceutical R&D spending ((rucore.libraries.rutgers.edu)); no percentage was available.

Attrition inputs are better documented. A **Tufts Center for the Study of Drug Development** benchmark of 187 protocols reported mean completion rates (completed over enrolled) of 77.8%, 70.5% and 67.6% for Phase I, II and III, with oncology far lower than non-oncology (([pmc.ncbi.nlm.nih.gov](https://pubmed.ncbi.nlm.nih.gov))). Screen failure averaged 31.5% in Phase II trials without decentralized elements (([pmc.ncbi.nlm.nih.gov](https://pubmed.ncbi.nlm.nih.gov))). These values should seed dropout and screen-failure ranges, but each therapeutic area needs its own assumptions.

Implications and Future Directions

Choose by layer. If the main risk is high-cost product with substantial demand variability, a tool that outputs overage and service level is the closer fit (Table 1). If the organization already runs SAP and needs ERP-native packaging and distribution, SAP ICSM's documented modules and approvals are relevant, with stochastic modeling to be confirmed. If the sponsor wants a vendor-neutral planner that may sit alongside any RTSM, Bluefin's stated model is relevant, with the Endpoint transition tracked. Signant's value proposition is a single supplier for forecasting, inventory and RTSM.

Proof-of-concept scorecard (evidence levels, not numeric scores). For each criterion record one of: demonstrated live with your data; documented in current vendor documentation; stated in marketing only; not evidenced. Criteria:

- **Reproducibility:** same inputs and version return identical outputs.
- **Assumption export:** enrollment, dropout, titration, shelf life and constraints are exportable.
- **Service level:** the target probability and the computed overage are shown together.
- **Expiry and campaigns:** scenario B in Table 2 is reproduced, including a second packaging lot.
- **Depot and site demand:** country and site demand views reconcile to the total.
- **Overrides:** role-based, reasoned, logged and reversible.
- **Integration:** a round trip with your RTSM and ERP test environments, with latency measured.
- **Validation:** supplier documentation mapped to your risk assessment.
- **Contracting and roadmap:** contracting entity, module licensing and ownership changes confirmed in writing.

Future direction. Vendors are adding agents and predictive features: Signant's four-agent bundle ((signanthealth.com)), SAP's predictive subject dynamics and the Bluefin and Endpoint stated aim of tying plans to execution data. The test for any such feature is whether it exposes assumptions and constraints that a quality unit can inspect.

Frequently Asked Questions (FAQs)

What is clinical trial supply forecasting software? Software that estimates kit demand from enrollment, dropout and visit schedules; some products add simulation and optimization ((www.informs-sim.org)).

How do Signant Health and N-SIDE differ for clinical supply? Signant bundles forecasting and planning with GxP inventory and RTSM ((signanthealth.com)). N-SIDE focuses on risk-based optimization and integrates with third-party IRT such as Suvoda ((suvoda.com)). Neither publishes a head-to-head benchmark.

What does N-SIDE clinical supply optimization produce? Per N-SIDE, minimum and maximum demand boundaries ((www.n-side.com)) and trade-offs across service level, inventory, waste and budget ((www.n-side.com)).

Does SAP offer clinical trial supply management? Yes. SAP Intelligent Clinical Supply Management has four modules ((learning.sap.com)) and documented IRT enrollment and forecast interfaces.

Is Bluefin part of Endpoint? Yes, per Bluefin's homepage ((bluefin.one)) and Endpoint's newsroom ((www.endpointclinical.com)).

What is the best clinical supply chain planning software? No independent evidence ranks these tools. Use the proof-of-concept scorecard and the reference trial above.

Can IRT systems do clinical trial supply simulation? Some vendors embed it, for example Clario's trial supply optimization ((info.clario.com)) and Calyx's consultant-run service ((www.perceptive.com)).

Conclusion

Selecting clinical supply forecasting software is a choice of planning layer and of integration contract, not a feature checklist. The public record supports describing what each vendor claims: Signant documents a suite with monthly cycles and a 2026 agent release; N-SIDE documents risk-based optimization with explicit overage outputs and an IRT partnership; SAP documents modules, scenario simulation, deterministic demand and approvals within an ERP landscape; Bluefin documents detailed release notes, depot and lot planning, and a recent move under Endpoint ownership. Independent performance benchmarks do not exist in the sources reviewed.

Buyers should therefore insist on evidence they generate: the reference-trial replay, exported assumptions, measured integration latency, a validation package mapped to their risk assessment, and written confirmation of roadmap, licensing and contracting entity. Pricing, module licensing and ownership details must be refreshed immediately before any decision, since several change frequently.

Source links

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