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# Building resilience in clinical trial supply chains

**A strategic framework for navigating trade policy and geopolitical change**

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# *Executive summary*

Recent tariff developments have the potential to impact clinical trial supply chains, and the implications for global investigational medicinal product (IMP) networks are subject to ongoing policy review and organizational assessment.

With more than **65% of global active pharmaceutical ingredients (APIs)** manufacturing occurring in China and India, clinical sponsors face direct exposure through shared contract manufacturing organization (CMO) infrastructure.[1] While current tariffs include exemptions for many pharmaceutical products from these regions, clinical trial supply chains remain exposed through:

1. Nonexempt materials such as excipients, packaging components and manufacturing equipment.
2. Evolving policy landscapes that create planning uncertainty.
3. Indirect impacts from supply chain reconfigurations affecting capacity and lead times.

This heavy reliance on a few regions means that shifts in global trade policy, regulatory environment, or geopolitical stability can have effects on clinical supply chains. Policy developments across multiple jurisdictions have included proposals for tariffs on imported pharmaceuticals and APIs.

Recent legal[2] and policy developments underscore that US tariff policy remains fluid following the Supreme Court ruling that the president does not have the authority to impose tariffs under the International Emergency Economic Powers Act (IEEPA). He imposed a **temporary 10% global tariff** under Section 122 of the Trade Act of 1974, **which the president has indicated could increase to 15%**. Though the Section 122 tariff will expire after 150 days (July 24, 2026) if Congress does not approve an extension, the president and administration officials have committed to initiating investigations under Section 232 and 301 trade authorities, which could lead to additional tariffs.

As a result, the defining risk for clinical trial supply chains is not any single tariff rate, but persistent uncertainty about scope, timing and duration.[3] To date, broad pharmaceutical tariffs have not been enacted, and exemptions have been granted for many pharmaceutical products. The policy landscape remains dynamic, with ongoing regulatory reviews—including Section 232 of pharmaceutical investigation—industry engagement, and evolving government guidance. Trade agreements announced in 2025 between the US and trading partners, including EU, South Korea, UK, and Japan, included provisions capping potential future pharmaceutical tariff rates, though not all of these deals have been fully implemented. Sponsors should monitor evolving policies closely and prepare for potential changes that could impact costs, supply reliability, and compliance requirements of research and development (R&D) operations.

**Supply chains**

***65% APIs***
concentrated in
**2 countries:**
**China** and **India**

**US tariffs**

***10%***
temporary global tariff

**Key timeline**
July 24, 2026:
Temporary tariff expires if not extended

2025:
Trade agreements announced to cap future tariff rates

# *The challenge*

Unlike commercial supply chains, clinical operations cannot absorb disruptions through inventory buffers or alternative sourcing without extensive regulatory approval processes. Every delay potentially risks first patient in (FPI) timelines, patient safety and trial integrity. FPI means the date the first human subject or patient is qualified for acceptance into a human clinical trial.

# *Why clinical trials are uniquely exposed:*

- **Fixed budgets with no cost pass-through:** Clinical trial budgets are locked at protocol development for the study duration, unlike commercial operations that can adjust pricing quarterly to offset cost increases.
- **Specialized, low-volume production:** Per-unit tariff costs disproportionately impact investigational products manufactured in small batches compared to commercial-scale operations.
- **Temperature sensitivity requirements:** Many IMPs and biologics require strict temperature control throughout their journeys, creating additional vulnerability when customs delays or extended routing threaten product integrity consistent with good distribution practice (GDP) principles implied in ICH E6.[4]
- **Extended regulatory response times:** Manufacturing changes for investigational products are governed by 21 CFR § 312.[5] The FDA requires a minimum of 30-day review periods for many changes, with complex modifications potentially taking **60 to 120 days**. Even though tariff measures such as Section 122 apply uniformly across countries, clinical trial supply chains face regulatory hurdles when adjusting suppliers or manufacturing processes. Any supply chain modifications prompted by policy changes, exemption status shifts, or other disruptions may introduce significant delays that commercial operations do not experience. This regulatory complexity means adjustments cannot be implemented quickly enough to prevent budget overruns or timeline delays, often resulting in missed FPI dates and protocol deviations that cascade through entire development programs.
- **Geographic concentration:** FDA analysis shows only **28% of US API facilities** are domestic,[6] while **China and India account for approximately 31%**. Major manufacturing hubs such as China and India remain exposed to broad US trade measures that may be applied uniformly across product categories under temporary authorities,[7] **with recent policy actions and analysis focused on flat tariffs of 10%**.[8] Although many pharmaceutical products may still qualify for exemptions, the temporary and changeable nature of these measures along with new potential sectoral or Section 301 tariffs creates planning instability for clinical supply chains that cannot quickly shift sourcing or manufacturing locations.

## Key statistics

***30 days***

The minimum FDA review period for many manufacturing changes

***60 to 120 days***

Potential review time for more complex modifications

***28%***

of API facilities supplying the US are domestic...

***31%***

... while this percentage are in China and India.

***10%***

Recent flat tariff actions and analysis have focused on this rate.

Importantly, many pharmaceutical products—including APIs, certain excipients and finished pharmaceuticals—currently benefit from exemptions. However, clinical trial supply chains remain exposed to risk through: (1) nonexempt materials essential to trial operations (packaging, equipment, certain excipients); (2) policy evolution that could modify exemption scope; and (3) the structural challenge that geographic concentration amplifies portfoliowide risk when any policy shifts occur, even those affecting only subsets of materials.

- **Patient safety imperatives:** These delays, as discussed, threaten trial milestones and patient outcomes.

# *The bottom line*

The sponsors who act decisively now to **build resilient clinical supply networks** can:

- **Protect** development timelines
- **Achieve** uninterrupted patient access
- **Weigh** direct and indirect tax opportunities
- **Mitigate** direct and indirect tax pitfalls (both compliance and financial)
- **Convert** volatility into sustainable competitive advantage while fulfilling their fundamental obligation to patients awaiting potentially lifesaving investigational therapies

# *The real impact:* Four barriers to clinical achievements

Through full analysis of recent policy and regulatory shifts, four barriers have been identified that may transform routine tariff adjustments into elevated challenges for clinical operations:

## *Barrier 1.*
### The fixed budget constraint

Clinical trials operate within confines that commercial operations do not. Budgets are locked at protocol development and are unable to flex when external costs spike. New tariff measures can impose unexpected additional duties across multiple Harmonized Tariff Schedule of the United States (HTSUS)[9] classifications, often with limited advance notice and unclear duration. Recent legal and policy developments indicate that US tariff policy remains fluid. Although many pharmaceutical products including APIs and finished drugs currently benefit from exemptions, clinical trial supply chains may still face exposure to broad-based tariffs applied across multiple input categories. As a result, the primary risk to clinical trial budgets is planning uncertainty rather than any single tariff rate.

For clinical trials, exposure persists through materials (certain excipients, packaging components, manufacturing equipment), policy volatility affecting long-term budget planning, and indirect cost impacts from supply chain reconfigurations. The fixed-budget constraint of clinical trials makes even modest cost variances challenging to absorb, regardless of whether costs stem from tariffs on nonexempt materials, supplier adjustments to navigate policy changes, or capacity constraints from broader market shifts.

**How to quantify the impact:**
Use the formula:

Δ Duty = Declared customs value × Additional duty rate × Eligible share of imports

to calculate incremental costs by product, supplier and shipping lane.

**What does this mean for clinical teams:**
Clinical sponsors are more likely to directly absorb tariff costs, unlike commercial businesses that may have more flexibility in mitigating cost pressures. This can force difficult trade-offs between study scope, patient enrollment targets and timeline commitments, often requiring scope reduction or midtrial budget reallocation when increases exceed planning thresholds established during protocol development.

## *Barrier 2.*
## The regulatory time trap

Tariffs may increase supply chain pressures, exposing clinical operations to regulatory time pressures that commercial operations do not experience. Investigational new drug (IND) requirements under 21 CFR § 312 mandate FDA notification for manufacturing changes, creating timeline impacts equal to the sum of regulatory review periods, supplier qualification processes and confirmation activities.

**How to quantify the impact:**
Timeline impacts include regulatory review, supplier qualification, method and process confirmation, and required amendments.

**What this means for clinical teams:**
While commercial pharmaceutical operations can switch to qualified suppliers within days or weeks to mitigate potential cost increases, clinical operations frequently require months to navigate regulatory requirements. This regulatory complexity means tariff-driven adjustments cannot be implemented quickly enough to prevent budget overruns or timeline delays, often resulting in missed FPI dates and protocol deviations that cascade through entire development programs.

## *Barrier 3.*
## The geographic concentration risk

The concentration of critical pharmaceutical manufacturing creates geographic chokepoints that expose entire clinical portfolios to systemic risk. FDA analysis reveals that only approximately 28% of current API facilities serving the US are domestically located, while China and India together account for roughly 31% of these critical facilities.[10]

**How to quantify the impact:**
Measure the share of materials sourced from single-country suppliers and assess the number of trials dependent on shared CMOs.

**What this means for clinical teams:**
Trade policies affecting major manufacturing regions may create cascading impacts across multiple trials simultaneously rather than affecting isolated products. A single country's policy action can affect an organization's entire development pipeline, leading to patient discontinuations, enrollment delays, and protocol amendments that implicate the ability to meet ethical obligations to trial participants.

## *Barrier 4.*
## The cold chain cliff edge

For temperature-sensitive investigational products, geopolitical and trade policy shifts may push operations toward a cold chain cliff edge where product integrity becomes critically vulnerable. Extended customs clearance, often due to increased inspections or regulatory changes, along with the forced rerouting impact critical window stability. For example, United Nations Trade and Development (UNCTAD) documented that Red Sea diversions have added 10 to 14+ days to shipping routes via the Cape of Good Hope.[11]

**How to quantify the impact:**
Monitor planned versus actual transit times and track temperature excursions on high-risk lanes; map stability-at-risk by shipping route and transportation mode.

**What this means for clinical teams:**
Unlike commercial products with temperature tolerance, investigational products face complete rejection if specifications are exceeded, necessitating costly emergency resupply efforts that directly jeopardize patient dosing schedules and trial timelines. Narrow stability windows are consumed in transit, leading to product loss, protocol deviations and missed dosing windows that can force patient discontinuations.

# A *strategic framework* for clinical resilience

A four-capability approach can move trial sponsors from reactive measures to proactive, patient-first resilience that maintains trial integrity while converting trade shifts into competitive advantage. A cross-functional "control tower" approach is recommended in order to take advantage of opportunities and mitigate potential pitfalls, including direct and indirect tax and tariff exemption options. Activities to build resilience, manage risk, and drive value are increasingly relevant for supply chain tax planning, as each strategic shift can have business model impacts with significant tax consequences. The potential tax opportunities (if well designed and implemented) can create competitive advantage, while the potential risks (where tax is not involved early) may have severe financial impacts as well as create delays for the physical flow of inventory.

## *Capability 1: Integrated risk intelligence and command center*

**Objective:** Establish visibility into tariff exposure while creating integrated monitoring systems that connect trade policy changes to specific trial impacts with actionable early warning.

**Solves for:** Visibility and intelligence gaps. Organizations cannot effectively respond to tariff changes without understanding their exposure landscape, and clinical teams typically learn about supply disruptions after they impact patient dosing schedules.

**Immediate actions (0 to 6 months)**

- Complete SKU-to-HTS mapping and quantify exposure using:
  Δ Duty = Customs value × Additional duty rate × Proportion of imports subject to duty
- Deploy 24/7 shipment visibility with exception alerts for all clinical lanes
- Pre-position 60 to 90 days of critical supply in bonded warehouses in low-tariff locations
- Connect trade policy intelligence to trial-specific impact assessments with sufficient regulatory lead time
- Tie enrollment forecasts to supply plans to prevent stockouts at sites

**Advanced capabilities (6 to 18 months)**

- Artificial intelligence (AI)-powered predictive analytics forecasting supply chain disruptions with automated response recommendations
- Integrated command center with real-time dashboards linking policy changes to trial-level risk and recommended actions
- Machine learning systems that trigger escalations based on predefined patient safety criteria

# *Capability 2: Resilient sourcing and trial continuity*

**Objective:** Build resilient supplier networks coupled with preapproved response protocols to reduce single-source dependencies and enable rapid activation of alternatives during disruptions.

**Solves for:** Alternative source and preparedness gaps. Single-source dependencies create unavoidable exposure when tariffs affect primary suppliers, while clinical teams typically react to disruptions rather than having preapproved response protocols.

**Immediate actions (0 to 6 months)**

- Prequalify at least one alternate CMO for each Tier 1 material through expedited qualification protocols
- Deploy 90-day safety stock of critical investigational products across multiple geographic regions
- Define site pause-and-restart criteria for high-risk geographies and shipping lanes
- Preapprove emergency rerouting to alternate carriers, ports of entry and distribution centers
- Establish late-stage customization operations (label and pack) in North America and EU regions to optimize duty treatment
- Check eligibility for import duty exemptions for clinical trial products and VAT reliefs for stock, label, and pack movements to optimize duty and VAT positions
- Build therapeutic area-specific playbooks for tariff and route disruption scenarios

**Advanced capabilities (6 to 18 months)**

- Qualify redundant manufacturing and release testing capabilities across multiple jurisdictions
- Architect regional supply networks that can rapidly pivot production and distribution as policy shifts
- Implement AI-driven models that link tariff changes to timeline impacts with automated insights and suggestions
- Implement AI agent providing real-time feedback on potential import duty and VAT impact, if any tariff changes
- Establish full contingency logistics and supplier networks with precleared regulatory pathways

# *Capability 3: Clinical tax optimization*

**Objective:** Strategically utilize trade mechanisms such as foreign-trade zones (FTZ), bonded warehouses, clinical trial exemption classifications, and duty drawbacks to reduce financial impacts without compromising regulatory compliance.

**Solves for:** Optimization gap. Clinical operations typically pay otherwise higher tariffs without leveraging available trade mechanisms because clinical teams historically focus exclusively on regulatory compliance rather than trade optimization.

**Immediate actions (0 to 6 months)**

- Identify options to use potential exemption classifications and strategies when importing
- Activate FTZ benefits at priority clinical depot operations
- Pursue duty drawback for eligible unused investigational products, returns and destructions
- Establish bonded warehouse operations in select clinical markets for duty deferral and flexible release timing
- Optimize HTS classification and documentation for duty benefits
- Activate import and other VAT reliefs at priority clinical depot operations, and VAT register relevant legal entities where required

**Advanced capabilities (6 to 18 months)**

- Design comprehensive clinical supply networks optimized for trade efficiency while maintaining full regulatory compliance
- Deploy automated systems that optimize classification, documentation, and claims processes to capture full eligible benefits
- Integrate tax-efficient routing and storage decisions into clinical supply planning processes

# *Capability 4: Clinical governance structure*

**Objective:** Establish dedicated governance framework with predefined decision rights and escalation protocols specifically designed for rapid cross-functional decision-making during supply-related patient safety scenarios.

**Solves for:** Coordination gap. Cross-functional decisions typically require weeks while patient-impacting supply issues need resolution in hours, because clinical supply decisions follow standard approval hierarchies designed for planned activities rather than crisis response.

**Immediate actions (0 to 6 months)**

- Establish a clinical supply crisis response team with immediate decision-making authority for patient-impacting supply scenarios
- Create a 24-hour escalation matrix tied to supply delays affecting patient safety, with clear decision rights
- Implement an executive steering committee with regular governance meetings, including clinical operations, regulatory affairs, quality assurance and global trade representatives
- Run tabletop exercises on realistic disruption scenarios to test response protocols
- Establish tax standard operating procedure (SOP) for the processes to achieve consistency and efficiency of all processes

**Advanced capabilities (6 to 18 months)**

- Embed all emergency procedures into standard clinical SOPs per ICH E6 guidelines
- Deploy automated decision-support systems that provide real-time recommendations and trigger escalations based on predefined patient safety criteria
- Integrate governance protocols with command center capabilities for seamless crisis response

**Example trigger:** "Cold-chain hold exceeding 48 hours initiates emergency resupply and regulatory notification protocol."

# *Planning considerations for the next 90 days*

Organizations should evaluate their resilience immediately. The following actions address short-term issues while establishing the foundation for broad transformation:

- √ **Map your exposure:** Complete HTS, origin and lane mapping for all IMPs and comparators; quantify duty exposure and stability-at-risk by shipping lane.
- √ **Secure options:** Prequalify at least one alternate source for each Tier 1 material; contract secondary logistics lanes and ports of entry.
- √ **Protect cold chain:** Enable lane-level temperature risk monitoring; define reroute criteria; prebook contingency capacity on critical shipping corridors.
- √ **Identify any tariff exemption opportunities:** Identify flows and options based on the intended importation flow.
- √ **Enable FTZ and bonded storage:** Activate FTZ use at one priority depot; establish bonded storage in one key market.
- √ **Formalize governance:** Finalize escalation matrix; run a tabletop exercise on a realistic disruption scenario.

# The *time to act* is now

While immediate priorities focus on managing current supply chain risks, organizations can simultaneously assess opportunities for reshoring or nearshoring manufacturing operations. These strategies can reduce future exposure to international trade disruptions, enhance supply chain control, and potentially position organizations to benefit from domestic manufacturing incentives that may accompany policy changes.

**Taking prompt action to enable compliance with evolving tax and trade regulations is essential to help mitigate risk and maintain operational continuity.** Any type of delay compounds the disadvantage as trade policy and regulatory requirements evolve. The trial sponsors who transform their clinical supply capabilities now can execute trials more efficiently while achieving uninterrupted patient access to potentially lifesaving investigational therapies.

**Timely management of supply chain disruptions is important for maintaining clinical trial schedules and supporting patient access to investigational therapies.** By implementing broad resilience strategies, organizations can help enable continuity in clinical operations and uphold their commitment to patient care.

## Key rules, initialisms and acronyms:

- **21 CFR § 312:** Title 21 Code of Federal Regulations Part 312 (Investigational New Drug Application)
- **API:** Active pharmaceutical ingredient
- **CBP:** US Customs and Border Protection
- **CMO:** Contract manufacturing organization
- **FDA:** US Food and Drug Administration
- **FPI:** First Patient In
- **FTZ:** Foreign-trade zone
- **GDP:** Good distribution practice
- **HTS:** Harmonized Tariff Schedule
- **ICH E6:** International Council for Harmonization Good Clinical Practice Guideline E6
- **IND:** Investigational new drug
- **R&D:** Research and development
- **UNCTAD:** United Nations on Trade and Development

# Endnotes


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