

SOLVING CRITICAL ISSUES IN CLINICAL TRIALS LOGISTICS

The Life Sciences & Healthcare sector is always looking to innovate and evolve clinical trials. New therapies, inclusive demographics, sustainability issues, and direct-to-patient trials are creating a new wave of innovative solutions.

The economic, political, and human health impacts of recent years have brought clinical trials into the public spotlight as never before.

Facing immense public pressures, existing practices have been under intense scrutiny. At the same time, personalized therapies based on gene technologies are changing nature of mass healthcare, while new statistical insights have revealed demographic, ethnic, and related methodology flaws. Vendors, LSPs¹, CROs², CMOs³, pharmaceuticals and biotech companies are facing fundamental revision to established practices.

DHL Life Sciences & Healthcare offers a comprehensive global logistics portfolio that is designed to meet exactly these challenges, with worldwide network operations, rigorous clinical and pharmaceutical governance, and incorporating high environmental standards. The DHL global network already connects tens of thousands of researchers, sponsors, and patients with compliant, safe, and robust distribution systems.

Clinical trials logistics professionals can take advantage of these established, trusted DHL networks to reach out to patients, laboratories and researchers across the world.

Additionally, with life sciences and healthcare experience stretching back for over 20 years, every DHL service is GxP compliant. With global operations running 24/7, DHL maintains constant regulatory vigilance, able to help and advise clients throughout every clinical phase.

Ultimately, DHL delivers the vital logistics that ensure clinicians and researchers are able to complete their work, improving health outcomes for all.

¹ Logistics Service Providers

² Contract Research Organizations

³ Contract Manufacturing Organizations



FOCUSED SERVICES FOR CLINICAL TRIALS



Clinical Supply Chain Management

Combining deep healthcare logistics experience with the power of a truly global network, DHL can consolidate the entire clinical supply chain for full transparency and continuous efficiency gains.



Clinical Supply Chain Visibility

DHL offers end-to-end visibility and control of clinical supply chains with customizable levels of monitoring.



Direct-to-Patient Clinical Trials

For the growing Direct-to-Patient clinical trials sector, DHL offers comprehensive solutions for direct delivery to and collection from patients. DHL delivers clinical trial materials, collects samples, and manages returns in pre-conditioned packaging.



IMP Storage & Distribution

Using carefully calibrated and continually monitored temperature-controlled storage, DHL IMP Storage and Distribution maintains product integrity and delivers time-sensitive, irreplaceable shipments through the global GMP depot network.



Packaging and Temperature Monitoring

Covering all temperature ranges: controlled, ambient, frozen to deep frozen. DHL offers a broad portfolio of packaging and data loggers, designed to protect the efficacy and integrity of treatments and samples, both in storage and transit.



Sample Logistics

DHL offers premium courier capabilities to ensure the safe and compliant transportation of biological samples from patients to laboratories, and anywhere in between, through a global distribution network.





DIRECT-TO-PATIENT

Today's trial participants expect high standards of care, and understand the value of their contribution. Robust, reliable, and responsive supply chain solutions are essential to provide low-stress, seamless clinical trial experiences that maximise patient retention rates.

Participants' expectations are heavily influenced by their own behavior as consumers. The ability to retain qualified patients in a study – especially those who are unable or unwilling to travel – can significantly affect the trial outcome and its associated costs.

For on-time, fully compliant home pick-up and delivery of clinical materials and samples, DHL will collaborate to build a customized Direct-To-Patient service. By increasing access to clinical trials with on-time, fully compliant home delivery and pickup of clinical materials and samples, CROs can meet these challenges and reach out to and retain a wider participant audience.

To reach patients at their homes, Direct-To-Patient service offers fast, flexible delivery from the clinical site, pharmacy, or central depot, with time-definite, priority handling.

The Direct-To-Patient service protects confidentiality by keeping full data privacy between patient and sponsor. On the return, the service includes collecting time-sensitive samples, again with timed pickup for delivery to the lab, with shipment prioritization where appropriate.

Typical business challenges include:

- · Reaching patients at their home
- · Picking up sensitive samples on time
- · Protecting patient confidentiality
- Maintaining temperature control
- · Complying with country regulations





Direct-To-Patient offering includes:

- Temperature control and visibility
- Specialist packaging for temperature-controlled hazardous goods (such as dry ice and high-quality smart sensors)
- Full returns process
- Real-time shipment monitoring 24/7/365

In addition, the service complies with appropriate country regulations, including:

- Good Distribution Practice (GDP) regulations
- Local, regional, and International Air Transport Association (IATA) regulations
- Dangerous goods compliant transportation; UN 3373
 Category B for biological items

KEY BENEFITS FOR YOUR BUSINESS



Reliable

Reliable, fast, flexible pickup/delivery to mantain treatment schedules.



Visibility

24/7/365 real-time monitoring with temperature control.



Patient convenient

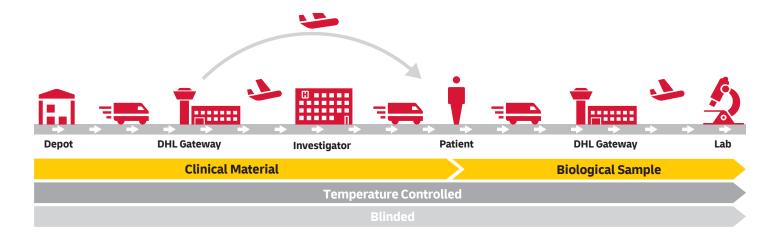
Home delivery improves patient retention rates.



Global network

Shipped via DHL's Global Distribution Integrator Network with specialized products for the Life Sciences sector or NFO.

ON-TIME, COMPLIANT HOME PICKUP AND DELIVERY OF CLINICAL MATERIALS AND SAMPLES



BIO SPECIMEN SAMPLE LOGISTICS

The investigation of patient samples is a crucial step in successful clinical trials. Speed and reliability are essential when shipping bio specimens to a central lab, combined with careful, compliant protection.

The Bio Specimen Sample Logistics solution combines expertise of DHL in life sciences and healthcare logistics with the global DHL network, ensuring on-time and compliant pickup and delivery of biological patient samples.

Typical business challenges include:

- Meeting short lead times for time-critical shipments
- Protecting sensitive bio samples
- Complying with dangerous goods regulations
- Meeting customs requirements

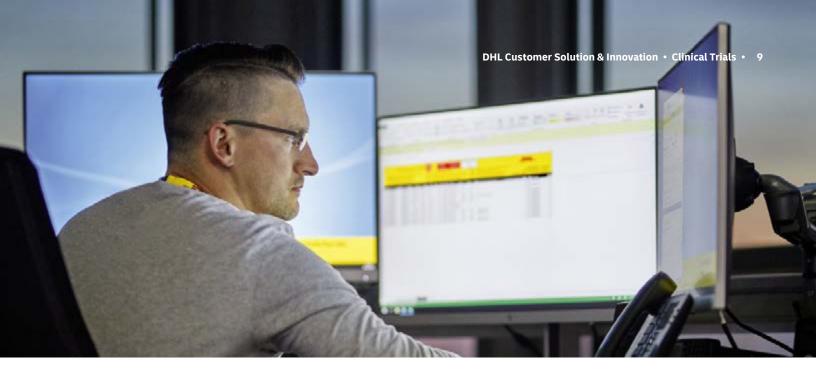
The service includes special provision for the short lead times that are often demanded for time-critical shipments. Bio Specimen Sample Logistics enables fast, flexible pickup and earliest possible delivery times, with short-notice booking.

To ensure protection for sensitive biological samples, the Bio Specimen Sample Logistics service offers specialist single- and multi-use packaging for temperature-controlled hazardous or dangerous goods. This includes dry ice and re-icing, liquid nitrogen, and remote and on-site temperature monitoring.

For all time-critical shipping and distribution of biopharmaceuticals such as antibodies, hormones, peptides, proteins and more, as well as human bio-products such as blood, cells and tissues, the DHL service includes full tracking and monitoring.

Naturally, the Bio Specimen Sample Logistics service can be used in combination with other DHL services, to create a solution that serves your exact delivery and collection needs.





The Bio Specimen Sample Logistics offering includes:

- · Priority handling
- · Active shipment monitoring
- 24/7 customer service
- · White glove services
- · Packaging return/refurbishment

In addition, the service complies with appropriate country regulations, including:

- Good Distribution Practice (GDP) regulations
- Local, regional, and International Air Transport Association (IATA) regulations
- Dangerous goods compliant transportation; UN 3373
 Category B for biological items

KEY BENEFITS FOR YOUR BUSINESS



Fast

Rapid, reliable, flexible pickup and delivery.



Peace of mind

Rely on DHL's trained experts around the world.



Visibility

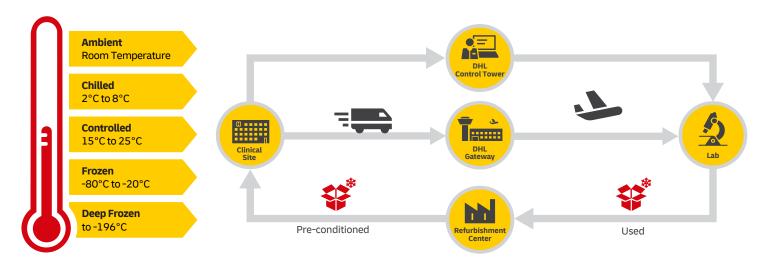
End-to-end shipment visibility to protect sensitive items.



Global network

Shipped via DHL's Global Distribution Integrator Network with specialized products for the Life Sciences sector.

ON-TIME, COMPLIANT PICKUP/DELIVERY OF SMALL, SENSITIVE SAMPLES FOR INVESTIGATION



KEY DHL LIFE SCIENCES & HEALTHCARE CAPABILITIES

The global DHL network provides a comprehensive suite of services that enables clinical trials managers to eliminate the complications of multi-vendor solutions and work with a single partner capable of meeting end-to-end logistics requirements.

With GMP/GDP-managed depots available worldwide combined with the dedicated Clinical Trials Center of Excellence, DHL offers very high assurance of supply.

DHL has served the clinical trials and commercial pharmaceuticals sector for more than 20 years with highly efficient, tailored operational solutions. Combined with deep understanding of clinical trials, DHL's solutions provide the much-needed capacity, flexibility, and scalability to solve global logistics challenges.

From urgent same-day packages to international cold-chain shipments, DHL provides reliable, robust, compliant, life sciences and healthcare services.

In addition, DHL's resources, capacity, and capabilities enable researchers and clinical trials managers to design entirely new logistics solutions – and all DHL services can be combined to meet the precise needs of each shipment or clinical trials project, creating a new world of opportunity.



FOCUSED SERVICES FOR CLINICAL TRIALS



Active monitoring

The network of DHL Customs
Control Towers, with active shipment
monitoring, enables global monitoring
of status and location, including
temperature and condition.



Compliance

DHL adheres to and is fully compliant with all international and incountry regulations and compliance requirements for the Life Sciences & Healthcare sector.



Sustainability

DHL Life Sciences & Healthcare is committed to achieving high operational and corporate environmental standards, from green transportation options to low-carbon packaging.



Capability, Capacity

DHL Life Sciences & Healthcare offers scalable capacity, including temperature-controlled capabilities, to meet rapidly growing demand.



Fleet Security

DHL operates its own air and land transportation networks, able to offer assurance of delivery and resilience in the face of adversity.





Centers of Excellence

DHL provides resources dedicated to innovation, best practice, and service efficiency, designed specifically to enable successful clinical trials.



Part of the DPDHL Group

DHL Life Sciences & Healthcare can draw on the deep resources of the world-leading DPDHL Group, offering global reach and resilience.



Flexibility

Clinical trials managers can select tried-and-tested same-day, overnight, and next-day solutions, while retaining full governance, control, and compliance.



Clinical Service Center

DHL's team of over 9,000 dedicated Life Sciences & Healthcare logistics specialist act as the central nervous system of your network. Our Accelerated Digitalization agenda brings innovation and contractual harmonization, through focused quality, operational execution, operational planning, and account management.

IMP STORAGE & DISTRIBUTION

Sponsors and CROs depend on the integrity, compliance, and on-time availability of investigational medicinal products (IMPs), with end-to-end visibility of time —and temperature— sensitive products.

The IMP Storage & Distribution service collects and delivers timesensitive materials, maintaining product integrity under rigorous conditions.

Typical business challenges include:

- · Ensuring global availability of medicinal products
- Providing IMP in time to adhere to patients' treatment schedules
- Maintaining regulatory compliance
- Assuring end-to-end temperature control and visibility
- · Releasing R&D budget for innovative drug development

This service is designed to ensure on-time product availability at the point of treatment. To adhere to demanding patient treatment schedules, the IMP Storage & Distribution service provides fast, flexible, and reliable materials distribution. All clinical shipments receive special care, available through DHL's global network.

The DHL IMP Storage & Distribution service follows GMP quality standards in all country, regional, and global depots. Facilities include the ability to transport and store products over a wide temperature range, from +25 °C to -196 °C, with shipment and condition visibility available at all times through global standardized systems and interactive dashboards.





The IMP Storage & Distribution service offers:

- Over 30 GMP depots, serving 32+ countries across all regions
- Storage and value-added services such as kitting and labeling
- More than 85% by volume handled within DHL-owned
- More than 200 DHL dedicated logistics personnel and 9,000 certified specialists



Explore more DHL warehousing capabilities

KEY BENEFITS FOR YOUR BUSINESS



Reliable

Fast, reliable, flexible pickup and delivery.



Global network

Best locations, optimal depot-investigator site proximity.



Visibility

End-to-end inventory visibility across all locations and in transit



Integrated

Global standar operating procedures (SOPs) and quality management system.



CLINICAL TRIALS LOGISTICS

IMP Storage & Distribution























Supplier

Pickup

Temp. controlled Storage



Export Transportation



Import

Temp. controlled Storage

Broker Turn Over

Regulatory

Final Mile

Patient

Inbour	
Store	
Track	
Deliver	
Recover	

ρι

Inbound transport

Deconsolidation

Global visibility & tracking tools

Next flight out service

Returns management

Global GMP depot storage network

GMP secondary packaging/Lab kitting

Global logistics control tower

Dedicated outbound transport

Certified destruction

GDP, GMP, GCP, Compliant; IMP License, GAMP5 Standards, G5 Principles

CUSTOMS CONTROL TOWER

Customs delays can derail time-sensitive clinical trials. Finding ways to move investigational medicinal products quickly, smoothly, and safely through customs and though import-export processes is essential for sponsors and CROs.

Controlling, organizing, and managing documents and customs activities can be a thankless task. Successful clinical trials depend on smooth coordination between the shipper and client countries.

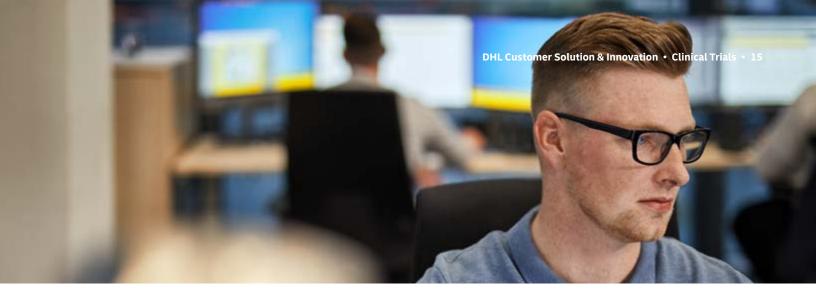
Long-distance links are especially vulnerable to many forms of disruption. For companies that depend on timely delivery of products, components and materials, the control of those risks is a strategic concern.

The Customs Control Tower solution for clinical trials managers enables full coordination, monitoring, and reporting on the flow of IMP imports/exports, and ensures product safety and regulatory compliance. Customs Control Tower is delivered by a global DHL team of customs experts with specialist training, able to help expedite time-sensitive clinical trials.

Typical business challenges include:

- Complying with a constantly evolving, changing regulatory landscape
- Preventing potentially lengthy and costly delays
- Identifying and avoiding bottlenecks
- Responding effectively to unexpected supply chain disruption





The DHL Customs Control Tower:

- Supervisory management at strategic, tactical, and transactional levels
- Qualified personnel experienced in customs brokerage, processes, and systems, with up-to-date IMP and clinical trials training
- Complete progress
 visibility with customized global reporting, post-shipment audit,
 and document archiving
- Full shipment monitoring using DHL Global Customs Connect
- Single point of contact and streamlined communication
- Business continuity planning and disaster preparedness
- Greater transparency and control, reduced administration for sponsors, and improved financials through greater control of duties and taxes

KEY BENEFITS FOR YOUR BUSINESS



Peace of mind

Trusted global partner with high compliance standards and security.



Fully customizable

A unique combination of services best suited for your requirements.



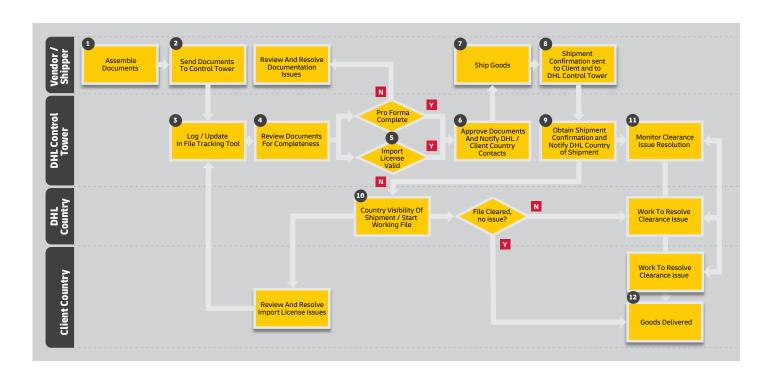
Single point of contact

Streamlined communications for all your customs-related needs.



Cost savings

Savings opportunities for duties and VAT, and identifying potential hidden costs.



FURTHER READING



PATIENT CENTRIC DELIVERY FOR **CLINICAL TRIALS OF THE FUTURE**

This paper looks to the future of clinical trials at a global scale, and how we respond to meet tomorrow's complex healthcare challenges.



VISIT THE DHL LIFESCIENCES & HEALTHCARE WEB PAGE

For healthcare to happen logistics must too. With the largest global healthcare logistics network, it's our responsibility to reach places and take on challenges that others can't. Because it's easy to say you care about healthcare, but another thing to show it.

Americas

Read more

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