



**INCEPTUA**  
CLINICAL TRIAL SUPPLY

**Inceptua  
Comparator Sourcing  
& Services**

**INCEPTUA**  
HELPING PHARMA · HELPING PATIENTS

# Inceptua Group

## INCEPTUA

CLINICAL TRIAL SUPPLY

One of the leading providers in global clinical trial comparator sourcing, packaging, labeling, and distribution solutions

## INCEPTUA

EARLY ACCESS

Experts in the strategy, design and implementation of global early access programs (managed access, compassionate use)

## INCEPTUA

PHARMA

A leading international specialty and rare disease pharma company with focus on Europe and the Middle-East



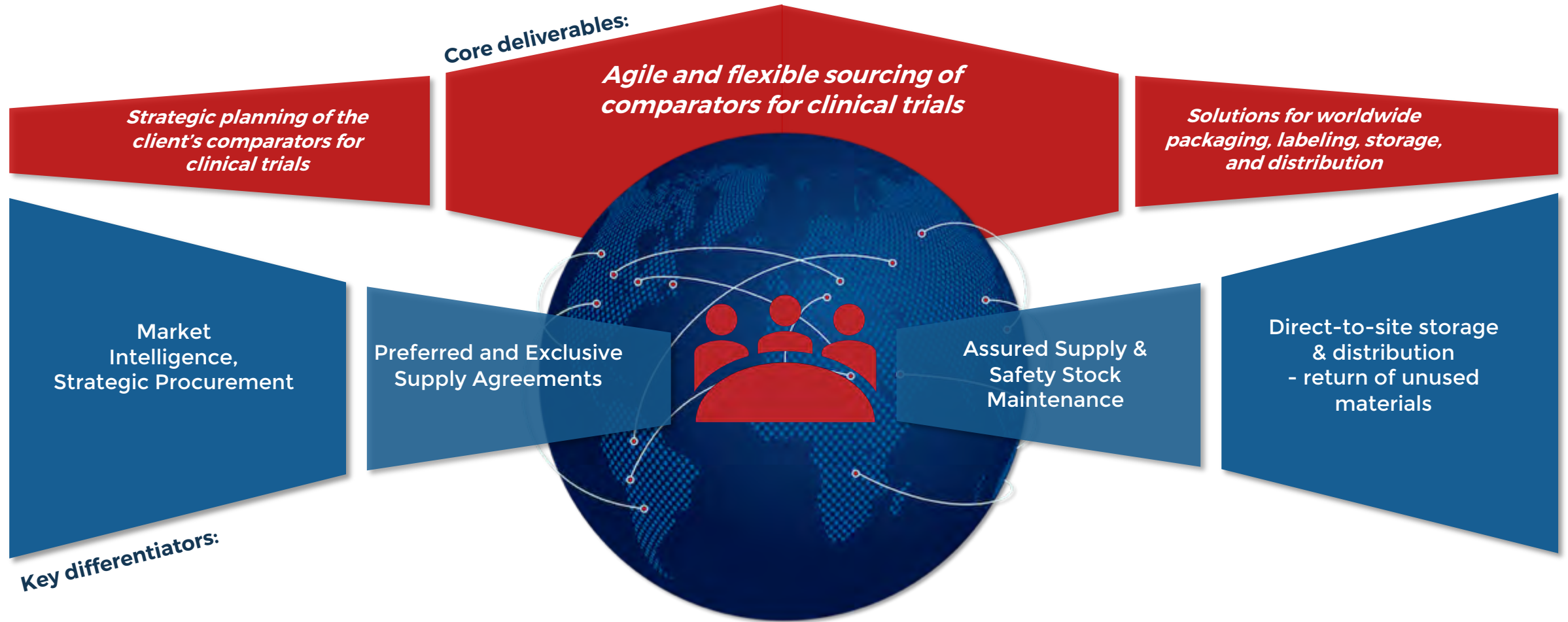
# Global and synergistic infrastructure

- Local presence across Europe, North America, and Asia

**Inceptua Group**  
Service Partner & Pharmaceutical Company



# Leading specialist partner for comparator sourcing and related clinical trial services



# Inceptua CTS drives strategic value for clients

- Strategic savings through preferred supply, exclusivity agreements, smart sourcing and access to over 110 qualified manufacturers and suppliers
- Supply Chain Financing options
- Uninterrupted supply through with risk mitigation and safety stock maintenance
- Reduced cost of overstocking or wasting unused material. Dynamic storage and direct-to-site solutions
- Global expertise, including market-leading support in China
- Dedicated, tailored service to specific client / study requirements

## Clinical Trial Services

Inceptua Clinical Trial Services helps you to identify and access the best possible solutions for your clinical trial supply needs





# Global Comparator Sourcing Reach and Partnering

- **Worldwide:**
  - >110 approved suppliers
- **Direct Access:**
  - Manufacturers
  - Nominated Distributors
- **Open Market**
- **Central, Local or Hybrid sourcing solutions**
- **Pharmaceutical and Food Grade Products**

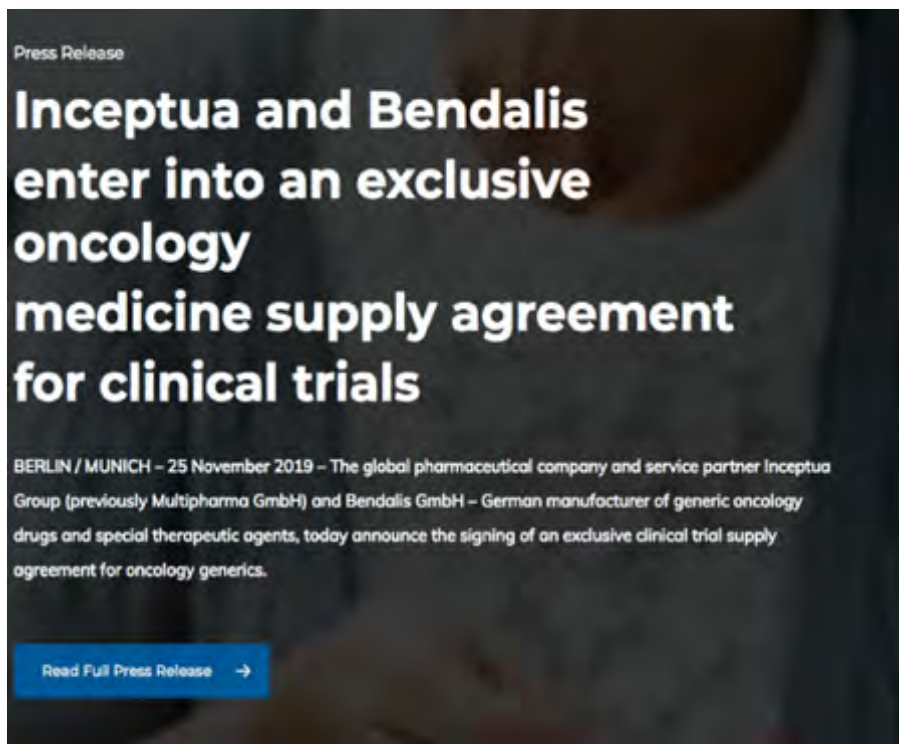
## List of Countries with Audited Suppliers and

**Partnerships:** Argentina, Australia, Austria, Belgium, Brazil, Bulgaria, Canada, **China**, Colombia, Croatia, Denmark, France, **Germany**, Georgia, Greece, Hungary, India, Ireland, Israel, Italy, **Japan**, Korea, Latvia, Lithuania, Netherlands, Norway, Philippines, Poland, Romania, Russia, Singapore, Spain, **Sweden**, **Switzerland**, Taiwan, **United Kingdom**, **USA**

## Sample List of Manufacturer Relationships and

**Partnerships:** Amgen, Bayer, Bendalis, BMS (and Celgene), Janssen, Medac, Merck, Novartis, Pfizer, Stada, Takeda, Teva

# Sourcing Oncogenerics in Europe



- **Direct access to manufacturers / exclusivity agreements such as Bendalis**
- Quick access to sizeable volumes of quality, Brexit-safe, Oncogenerics
- Mitigation against stock-outs or manufacturing issues that may otherwise lead to delays
- Preferred pricing through Inceptua and
- The ability to reduce spend on overage more accurately
- Support all orders with CoA, CoC, SPC and MSDS
- Documentation allows us to import into China

## Key Products

Calcium folinate
gemcitabine
5FU
carboplatin
irinotecan
oxaliplatin
paclitaxel
doxorubicin
epirubicin
fludarabine
docetaxel
vinorelbine



# Inceptua in China

- Actively operating in China for 20 years
- Local Operations – Project Management and Sales
- GSP Partner with wholesale license including VAT invoicing
- Direct access to China-registered products
- Mandarin speakers based in China and outside of China
- Key Manufacturer Partnership in place with Hansoh and Hengrui



# One-Stop-Shop Clinical Trial Services

Minimize study costs and  
maximize efficiency



Combine Inceptua's expertise in  
strategic sourcing with our  
harmonized service provision







STORAGE | PACKAGING |  
LABELING | DISTRIBUTION

## Inceptua's Services

- Consultation on Open and Blinded packaging and labelling solutions
- Receipt, handling, storage and distribution of non-IMP and IMPs according to GMP regulations
- Secondary clinical packaging and labelling:
  - Label design and production
  - Full IMP labelling including special label production and application (e.g. booklet, blister and wrap labels); nIMP labelling e.g. "for clinical trial use only"
  - Customized repackaging and kitting solutions including carton boxes, kit assembly / patient supply kits, and application of tamper evident seals
  - Expedited turnaround provides for "just-in-time" packaging and labelling solutions
- Development, translation, and distribution of site instructions
- QP release and QP certification (including after EU import)
- 24/7 Emergency / rescue medication rapid-response distribution
- Proactive inventory management
- Return, reconciliation, and destruction

# 'One-Stop-Shop' Service in Key Locations

-  Managed oversight and expert management of projects
-  Site-driven ordering with centralised controls, providing responsive study-sensitive supply
-  Proactive monitoring of supply levels, reducing burden on client oversight
-  Dedicated service with allocated expert resources managing projects regardless of size
-  No waiting in line for a manufacturing spot
-  Centralised, local or regionalised packaging and labelling tailored to specific needs
-  Harmonisation with Inceptua's supply of study medicine provides dynamic control of overage and reduced study costs
-  Quick response and turnaround times
-  Partnering to provide efficient and flexible services to clients with key providers

Capability					LATAM, Other- Asia and ex-EU
Customised Secondary Packaging / Labelling of nIMP and IMP	✓	✓	✓	✓	CT Use Only Labels
Study-Dynamic Storage and Distribution	✓	✓	✓	✓	✓
Label Design and Printing	✓	✓	✓	✓	✓
Open and Blinded Studies	✓	✓	✓	Open Only	Open Only
Cold-Chain Labelling	✓	✓	✓	✓	Variable
Rescue Medication Rapid-Response	✓	✓	✓	✓	✓
Returns, Reconciliation and Destruction	✓	✓	✓	✓	✓






# Optimized Global Depot Storage and Distribution Solutions

- With access to depots in over 50 countries Inceptua tailors supply chain strategy and services to the needs of each clinical trial
- Regularly audited and qualified global partners to highest EU GxP standards
- GDP compliant transportation with a careful eye on your study budget
- Traceable delivery of both ambient controlled and cold chain shipments with Just-in- Time (JIT) capabilities
- Shelf-Life control via oversight
- Regional project management ensures rapid response times
- Return, reconciliation and destruction of excess, used and unused IMP, coordinated through a single point of contact
- Central, Regional or Local optionality
- IXRS supported studies via email instruction
- Proactive inventory management further enhanced through use of Inceptua's online site-order portal with central oversight
- Peace of mind from Inceptua's secure, direct, safe, and efficient supply chain

# Local (in-country) Clinical Trial Services: Sourcing, Packaging, Labelling, Storage and Distribution

America	Europe	Asia + Australia	Africa
USA	EU 27	China	South Africa
Canada	United Kingdom	Japan	
Brazil	Switzerland	India	
Argentina	Israel	Indonesia	
Chile		Hong Kong	
Colombia		Malaysia	
Mexico		Philippines	
Peru		Singapore	
		Taiwan	
		Thailand	
		Vietnam	
		Australia	

-  ➤ Local sourcing is available in addition to other services or independent of them
-  ➤ Local sourcing is only available in combination with other Services
-  ➤ No local sourcing, but other Services are available

## Commitment to Quality

1. We only work with leading manufacturers, well established CMO's, wholesalers, and warehouses
2. We only partner with the top performers in each region
3. We are audited by Swissmedic (CH), MHRA (UK), LAGeSo (DE), PMDA (JP), New York Board of Pharmacy (US) as well as numerous customers and business partners

*Our Global Quality system ensures all services are executed under GMP and GDP standards*





