



## SERVICE CATALOGUE

# About Alcura

## WHO WE ARE

At Alcura, we specialise in services for Clinical Trials, supporting both local and global studies, with more than 30 years in drug supply, packaging and clinical trial distribution.

We offer comprehensive support in all phases of clinical trials and we also work with patients, through programs for hospitals and companies, offering them support and help in their treatments. Our team understand the importance of flexibility and are mindful of the patient in every trial.

## WE ARE PROUD TO SUPPORT:



CLINICAL RESEARCH  
ORGANIZATION (CRO)



MANUFACTURERS / SPONSORS



HEALTH PROFESSIONALS/ HEALTH  
INSURERS/ CLINICAL HEALTH FUNDING  
AGENCIES



PATIENTS

# Our experience

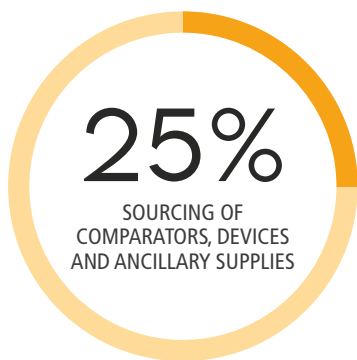
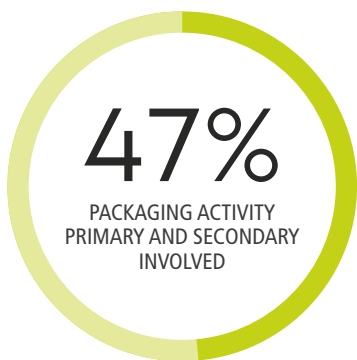


340+

INTERNATIONAL PROJECTS  
Clinical Trials each year

249+

PHASE II OR PHASE III  
Most of the international projects,  
are Phase II or Phase III.



# Worldwide coverage

Alcura is a Global provider of specialized Clinical Trial dedicated services, headquartered in Barcelona (Spain). Alcura’s global network spans all continents: Europe, North America, Latin America, Asia Pacific, Africa and Oceania.

Our international reach allows us to help research teams, pharmaceutical companies and contract research organisations (CROs) ensure proper logistics for their clinical trials in various countries.



Alcura’s **new logistics center** built in 2021 and located in Barcelona (Spain) with capacities of:



Our **Clinical Trials** dedicated team in Spain delivers worldwide coordination and support, ensuring a timely delivery of the clinical medication to our patients.



Cencora is a leading pharmaceutical solutions organization centered on improving the health of people and animals around the world.



\$230B+

REVENUE

Growth aligned with our customers’ long-term success.



1.300+

GLOBAL LOCATIONS

Delivering a range of services to address specific, local needs.



46.000+

TEAM MEMBERS

Diverse expertise all focused on improving global health.

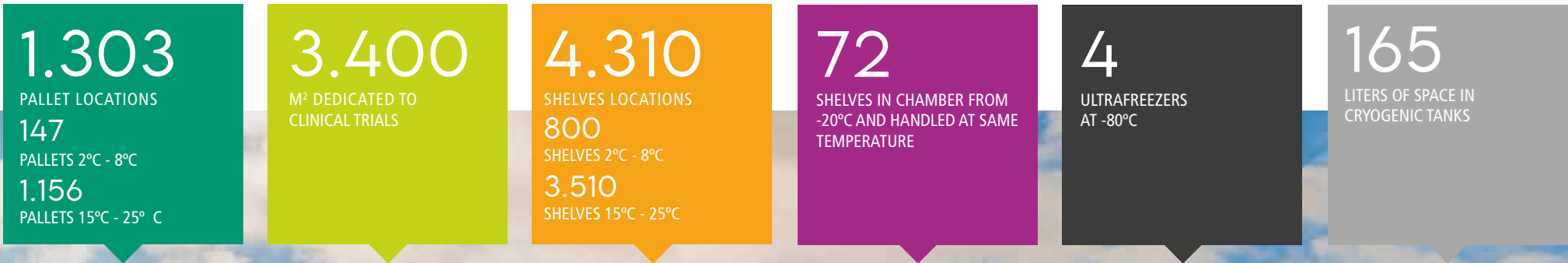


50+

COUNTRIES WITH A LOCAL PRESENCE

Growing knowledge of market-specific healthcare environments.

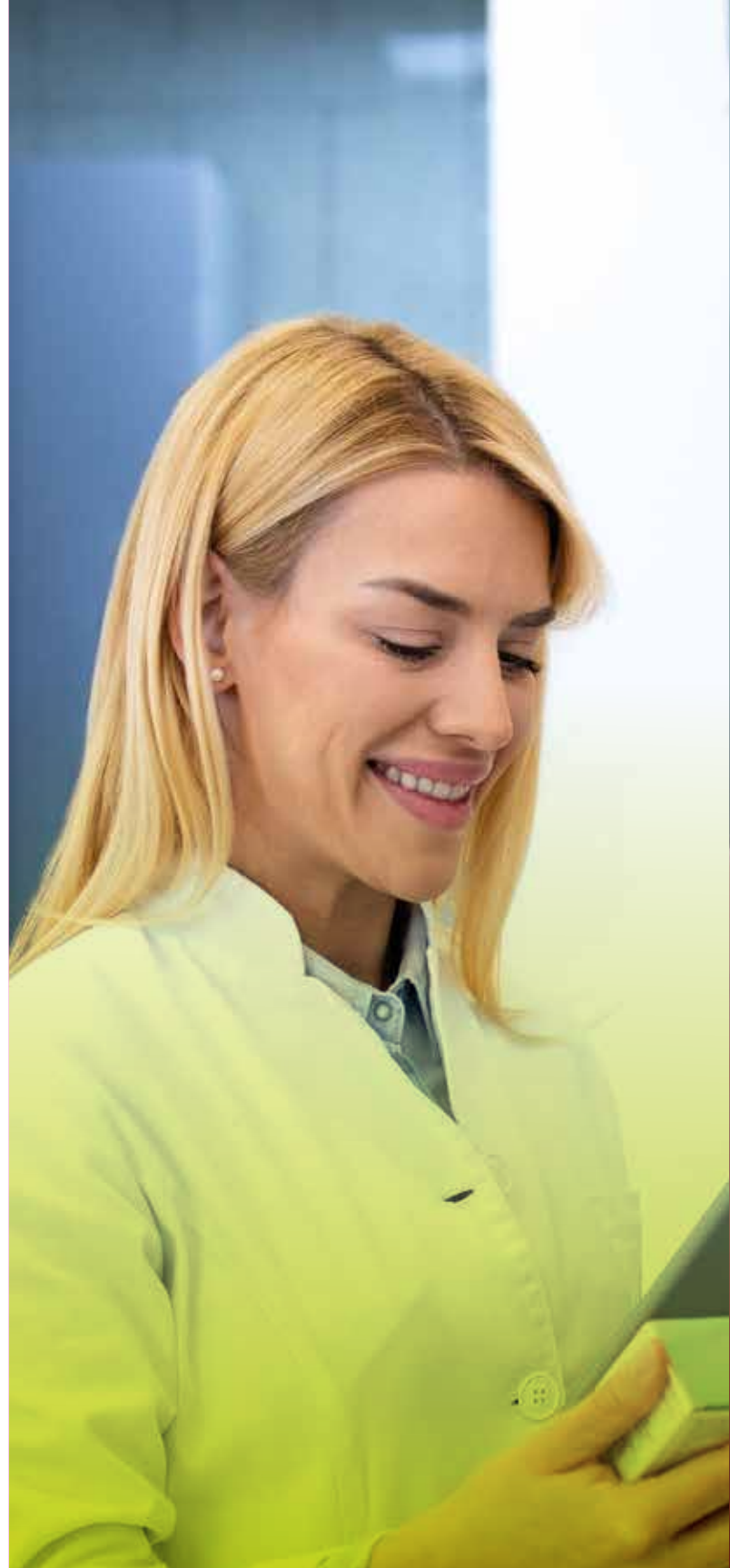
WE ARE UNITED IN OUR RESPONSIBILITIES TO CREATE HEALTHIER FUTURES





OUR SOLUTIONS

# Clinical Trials Solutions



SOURCING OF COMPARATORS,  
MEDICAL DEVICES AND  
ANCILLARIES



CLINICAL TRIALS  
SUPPLY MANAGEMENT



PATIENT SUPPORT  
PROGRAMS (PSP)

OUR SOLUTIONS

# Integrated solution

Integrated solution for clinical trials, from: design, providing service and value throughout its journey. Search, purchase and supply of medication or medical devices, clinical trials logistic management in all its phases. Importation, packaging, storage, distribution, return and destruction.



SOURCING OF COMPARATORS,  
MEDICAL DEVICES AND  
ANCILLARIES



CLINICAL TRIALS  
SUPPLY  
MANAGEMENT



PATIENT SUPPORT  
PROGRAMS (PSP)



340+ CLINICAL TRIALS



GDP



ISO9001:2015



GCP



GMP



LOPD CERTIFICATE



## OUR SOLUTIONS

# Sourcing of Comparators, Medical Devices and Ancillaries

## Supply of medication and medical devices.

Access to reliable medicinal products and materials for clinical trials is key to the success of any clinical trial. As a trusted supplier of comparators, Alcura delivers the right product to customers, at the right time, through:



- 1 Robust **procurement strategies**.
- 2 **Direct communication** with the manufacturer.
- 3 **Supply of products** from the same batch.
- 4 **Adjusted supply quantity** for each phase.
- 5 **Support** to short and long term CT.
- 6 **Cost and time reduction** of supply.
- 7 **Transport** with specialized supervision.

## Pharmaceutical sourcing

- Multi-country global procurement, with local knowledge of requirements and restrictions.
- Access to network worldwide including the supply chain distribution at a local level.
- Decommission of medication - FMD.
- Sourcing directly from manufacturers assuring provenance, integrity and custom manufacturing linked to the different phases of the Clinical Trial.
- Supporting the pharmaceutical sourcing by:

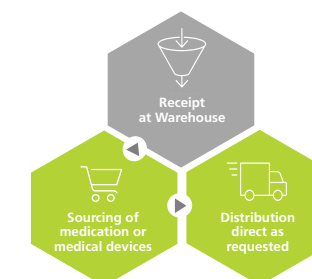
STRICT SUPPLIER  
AND CLINICAL  
SUPPLY CHAIN  
QUALIFICATION  
PROCESSES

TRACEABILITY,  
ACCOUNTABILITY,  
AND RECONCILIATION  
OF PRODUCTS

SECURE SUPPLY  
FOR THE DURATION  
OF THE TRIAL  
AND PRODUCT  
SAMPLES AND  
DOCUMENTATION

PRICING,  
AVAILABILITY,  
AND LEAD TIMES  
INSIGHT

INSPECTION  
PROCEDURES  
AND WITHDRAWAL  
OF PRODUCTS



## OUR SOLUTIONS

# Clinical Trials Supply Management

## Assessment of the design of clinical trails with drugs

Alcura supports more than 300 clinical trials per year.  
With our know-how, we can advise and support on:

- Assessing the project management with new approaches to the future.
- Approach to supply chain, manufacturing and distribution.
- Optimization of the design to adjust timeline and costs.

## Importer of Record (IoR)

We manage importation in: Europe (EU, UK and Eastern Europe), USA, Asia and Africa, thanks to the excellent knowledge of local requirements allowing to speed-up the importation process.

## Primary and secondary packaging

Alcura has the capability to act as CMO manufacturing and releasing batches of drugs for phase I-IV clinical trials.

### PRIMARY PACKAGING

MANUFACTURING  
OF PLACEBO IN  
SOLID FORMS

AUTOMATED  
COATING

OVER-  
ENCAPSULATE  
OF DRUGS FOR  
DOUBLE-BLIND  
TRIALS

PACKAGING  
(BLISTERS, BOTTLES,  
VIALS, AMPOULES)

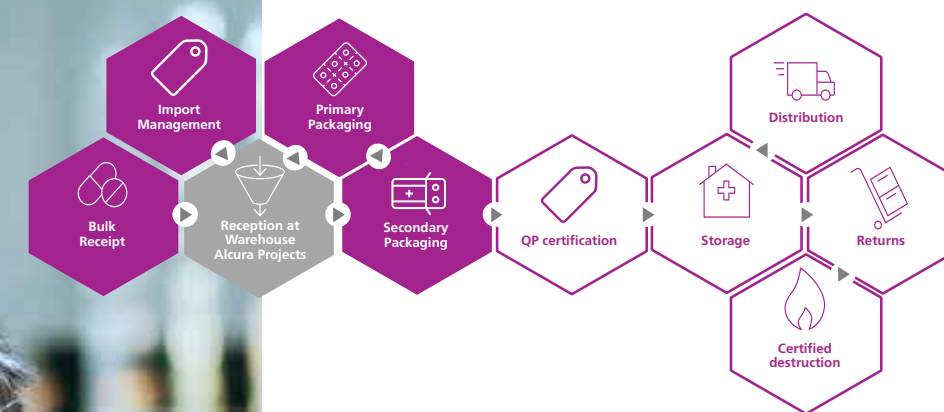
PACKAGING -  
LABORATORY KITS

BOTTLING  
OF SOLID FORMS

### SPECIAL TEMPERATURE CONTROLLED AREAS FOR PRIMARY PACKAGING

15°C TO 25°C

Alcura can manufacture liquid forms of placebo and reach 2 - 8°C using a partner in USA.



### SECONDARY PACKAGING

DESIGNS OF  
DIFFERENT KIND  
OF LABELS  
(SIZE, LANGUAGES, BOOKLETS)

MANAGEMENT OF  
LABELLING AND  
RELABELLING

KIT PRODUCTION  
ANY TYPE OF  
ANCILLARY  
(BAGS, TUBES,  
THERMOMETERS,  
ETC)

DESIGN AND  
MANUFACTURING  
OF BOXES

### SPECIAL TEMPERATURE FOR SECONDARY PACKAGING

15°C TO 25°C

2°C TO 8°C

-20°C

-80°C\*

\* Medication will be labelled in a  
-20°C room or 2-8°C with dry ice.





## QP certification

Our qualified teams handle all investigational drugs in accordance with strict operating procedures to ensure quality throughout the distribution. All our facilities are subject to the supervision of pharmacists and operate according to strict standards operating procedures.

## Quality control

- 1 Once medication arrives to the EU, a **QP Release process is necessary to be completed**. This is mandatory based on EU Regulation (GMP)
- 2 **Batch testing of medication will be required** when there is no Mutual Recognition Agreement (MRA) between the manufacturing country and EU.
- 3 Once medication is released it can be **distributed to sites (EU and/or non EU)**.



GDP



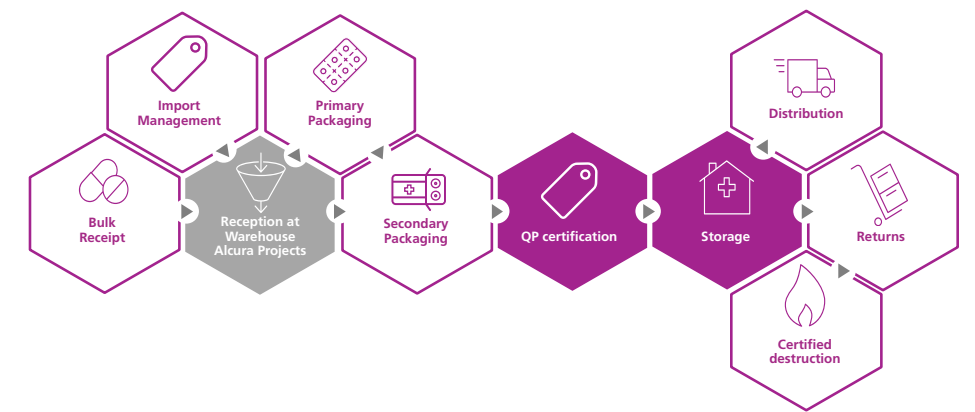
GCP



ISO9001:2015



GMP



## Storage and distribution of investigational medicinal products

### STORAGE CAPACITIES

Special storage controlled areas for all types of IMP, commercial and Medical Devices:

CYTOSTATIC

NARCOTIC DRUGS  
& PSYCHOTROPIC

BIOLOGICAL  
PRODUCTS

BLOOD DERIVATES,  
ADVANCED  
THERAPY  
MEDICINAL  
PRODUCTS (ATMP)

CHEMICAL  
SYNTHESIS  
MEDICATION

MEDICAL  
DEVICES

GMO  
(TYPE I & II)



**Ambient**  
(15°C - 25°C)

**Cold**  
(2°C - 8°C)

**Freezer**  
(-20°C - -80°C)

**Cryostorage**  
(-196°C)

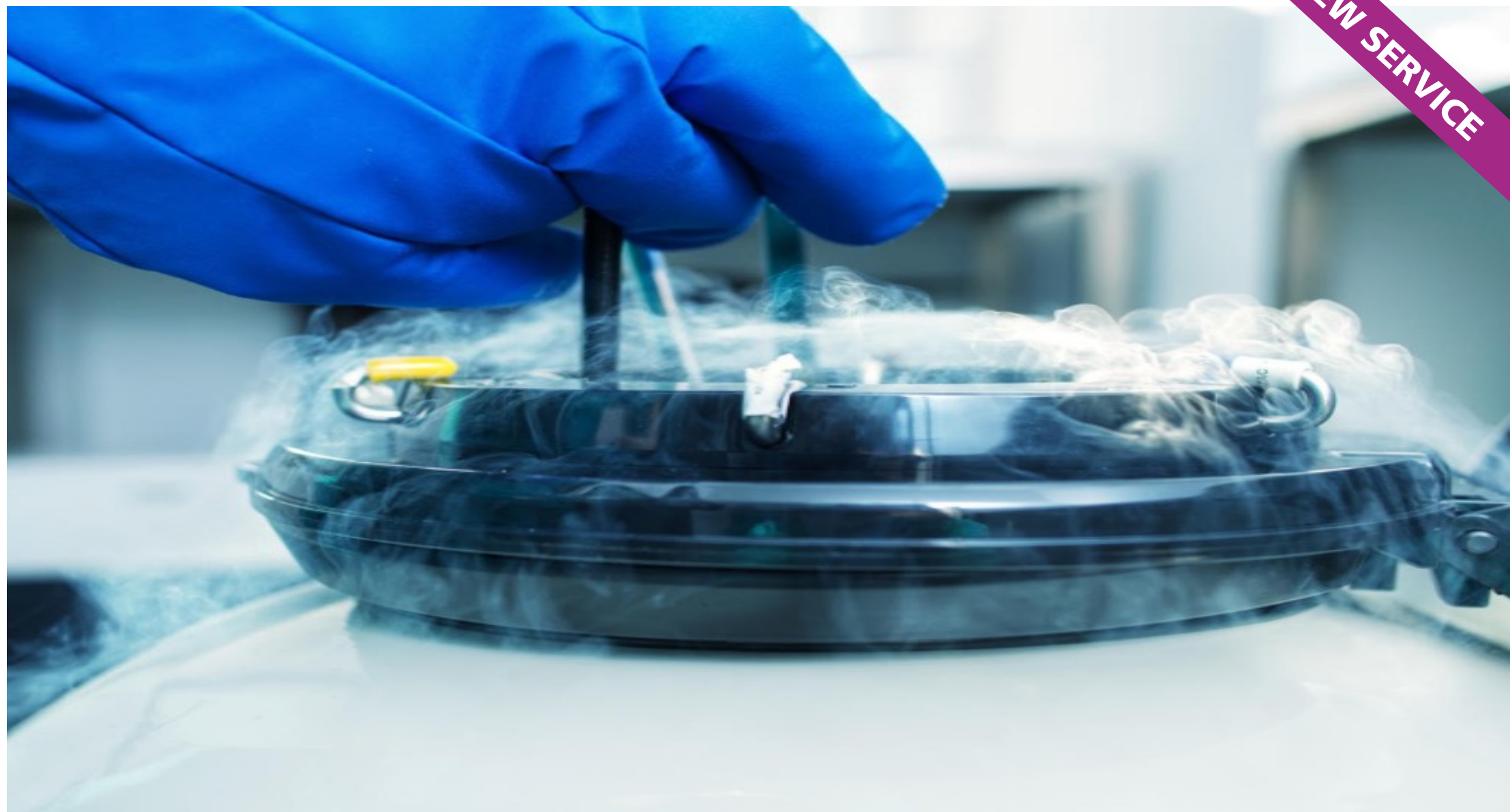


## Cell and Gene Therapies Management

Alcura is committed to supporting innovation and new advanced therapies. For this reason, at the beginning of 2023, we launched our new capabilities to manage clinical trials for cell and gene therapies (CGTs).

MIA (Manufacturer's Importation Authorization) enables Alcura to import and release investigational CGTs from any part of the world and ship them in & out of Europe, in all ranges of temperatures, including Cryostorage.

Alcura is driven by versatility when understanding the client requirements offering an End-to-End service for these special therapies.



### Cell & Gene Therapy

#### COLLECTION AND DISTRIBUTION



**Delivery of 99.91% of shipments** on time and within range.

#### MANUFACTURER AUDIT



Review of the Supply Chain roles and Qualified Persons **for CGT declaration.**

#### REGULATORY ASSESSMENT



**Regulatory** advice in CGT landscape.

#### RELEASE OF THE THERAPY IN EU



**Batch certification of CGT** products in EU.

#### IMPORTATION & EXPORTATION



**Import license for CGT medicinal products.** Specialized GDP team for CGT services.

#### STORAGE AND MAINTENANCE



Controlled storage of CGT; **all temperature ranges** including **Cryostorage.**

#### SECONDARY PACKAGING



Controlled **secondary packaging** of CGT following EU rules.

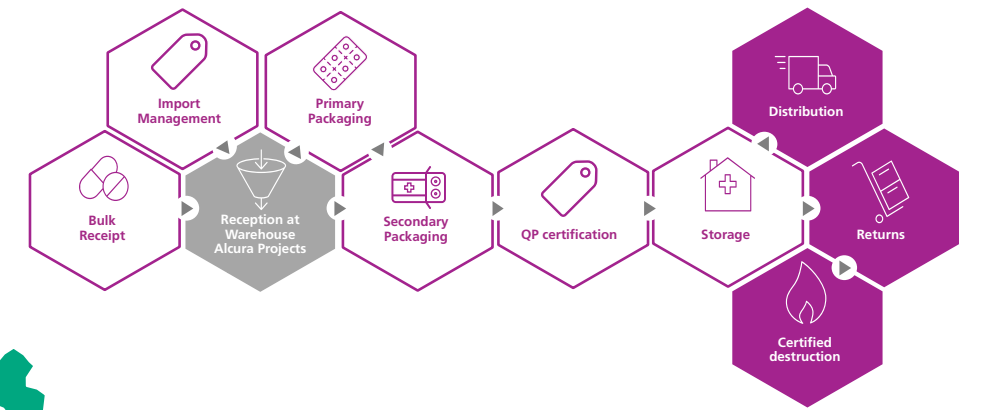
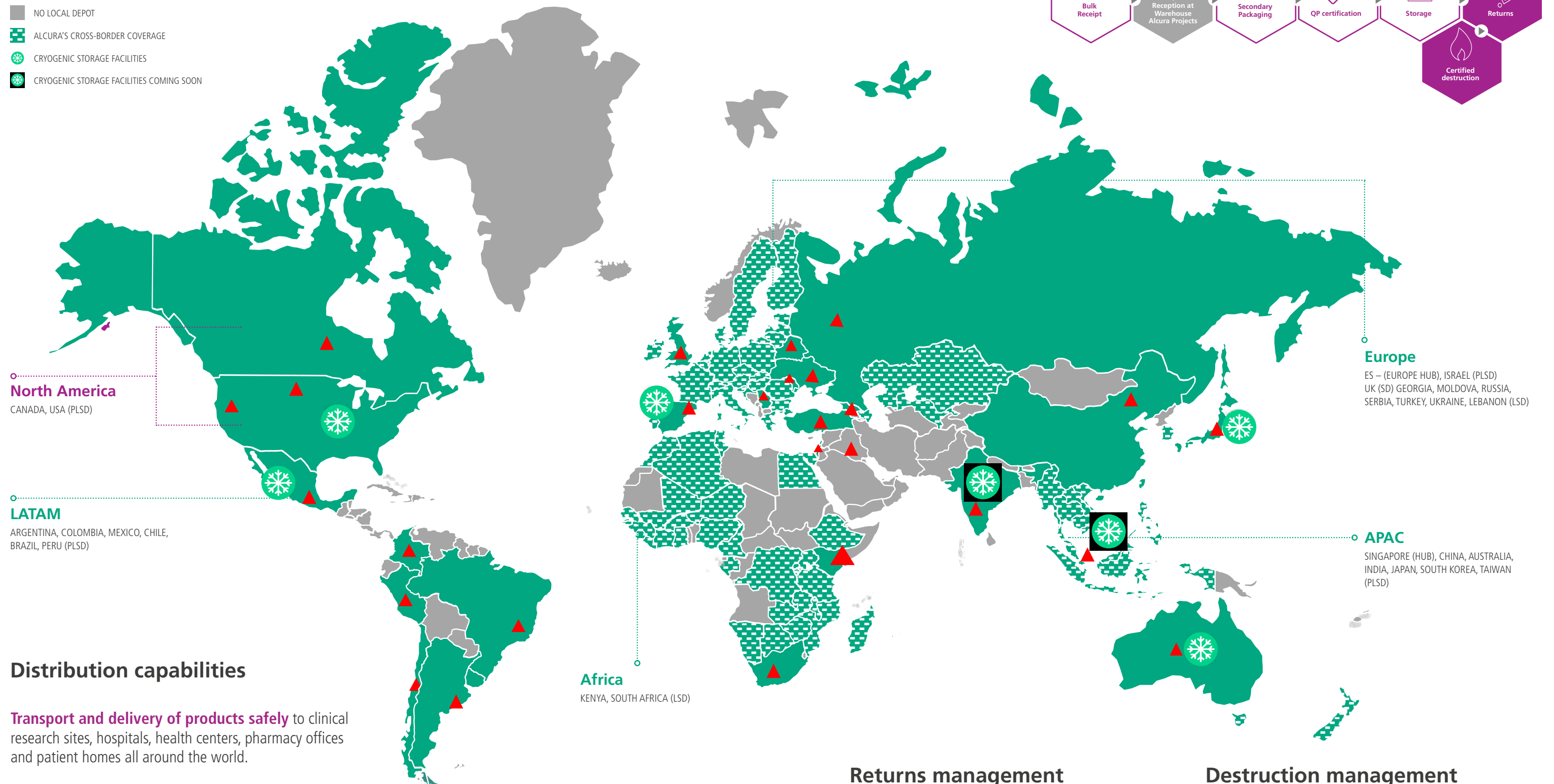
#### RETURNS AND DESTRUCTION



Capability to **return and destroy** according to the applicable laws.

## Warehouse management (global network)

- ALCURA'S PRESENCE (OWNED AND OUTSOURCED)
- NO LOCAL DEPOT
- ALCURA'S CROSS-BORDER COVERAGE
- CRYOGENIC STORAGE FACILITIES
- CRYOGENIC STORAGE FACILITIES COMING SOON



## Distribution capabilities

- Transport and delivery of products safely** to clinical research sites, hospitals, health centers, pharmacy offices and patient homes all around the world.
- Cold chain guaranteed** through qualified active or passive packaging solutionse.
- Agreements** with national and international courier companies.
- Distribution direct** to site through our validated logistics partners.

## Returns management

### OUR REVERSE LOGISTICS MANAGEMENT SERVICES INCLUDE:

- ✓ Collection of used and unused medication.
- ✓ Content control and reporting.
- ✓ Relabeling and/or reallocation.
- ✓ Storage in specific and restricted areas.
- ✓ Collection and removal of clinical waste.

## Destruction management

### POST-STUDY, WE MANAGE THE DESTRUCTION OF REMAINING STUDY MATERIALS:

- ✓ Certified destruction of medication of special control, cytostatics and biological products.
- ✓ Inertification and incineration.



OUR SOLUTIONS

# Patient Support Programs (PSP)

**Alcura focuses on making life easier for patients by helping them to manage and maintain their health at home, and increase in this way their adherence to the treatment.**

The PSPs have a positive impact on different stakeholders, such as patients, doctors and manufacturers, as well as the healthcare system.

The PSPs boost the patient empowerment and support on its disease by reducing the hospital stress and improving adherence.

PSPs the value proposition of the drugs by offering value-added services both to the patients and healthcare system.

Optimization of healthcare resources is another benefit of the PSPs.

## WHAT ALCURA'S PROGRAMS OFFER



### HOME CARE

At Alcura, we design and develop programs to provide patient-based care at home to increase patient's quality of life (eg. support on home infusion).



### HOME DELIVERY

Coordination of the delivery of commercialized drugs from the hospital to the specialized center. Support on the delivery of the IMP at patient's home (DtP).



### CALL CENTER

Support on patients doubts and coordination of different services to ensure adherence's treatment. Pharmacovigilance services to ensure adverse events notifications.



### TRAINING & COACHING

Development training sessions for patient's self-administration of complex drugs. Training of nurses and hospital events aimed at prevention campaign





