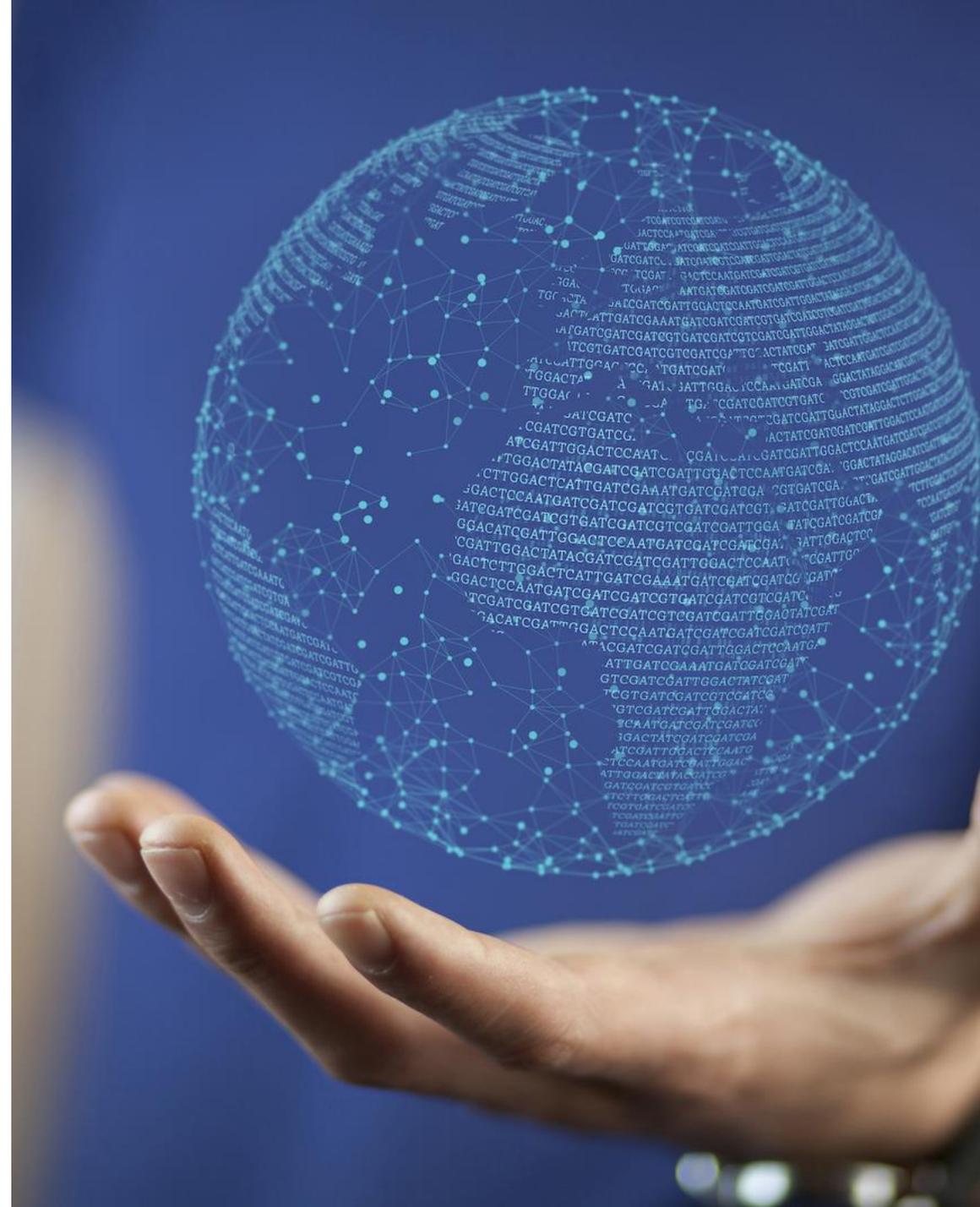


Sourcing for Your Clinical Supply Chain

Labelling, Packaging, Storage and
Distribution



Who we are



Lucas Lucero

Vendor Management Associate Director

As a **Vendor Management Associate Director** in the **Logistics and Clinical Supply** department, I focus on building strong vendor relationships to ensure an efficient and reliable supply chain. With over eight years of experience in procurement, vendor performance management, and planning, I understand the essentials of successful vendor partnerships. Previously, I developed global sourcing strategies as a Supplier Relationship Manager for CMOs in pharma, equipping me with the skills to manage and optimize vendor collaborations.



Marina Recalde

Vendor Manager

As a **Vendor Manager** in the **Logistics and Clinical Supply** department, I manage vendor relationships to ensure the efficiency and reliability of our supply chain. In my previous role as a Quality Assurance Manager, I was responsible for overseeing supplier compliance and quality management. This background has provided me with a comprehensive understanding of the regulatory standards necessary to uphold high-quality vendor partnerships.

Agenda



Introduction



Vendor Qualification



Qualified Vendor Selection



Q&A

1

Introduction



Presentation Objectives & Scope

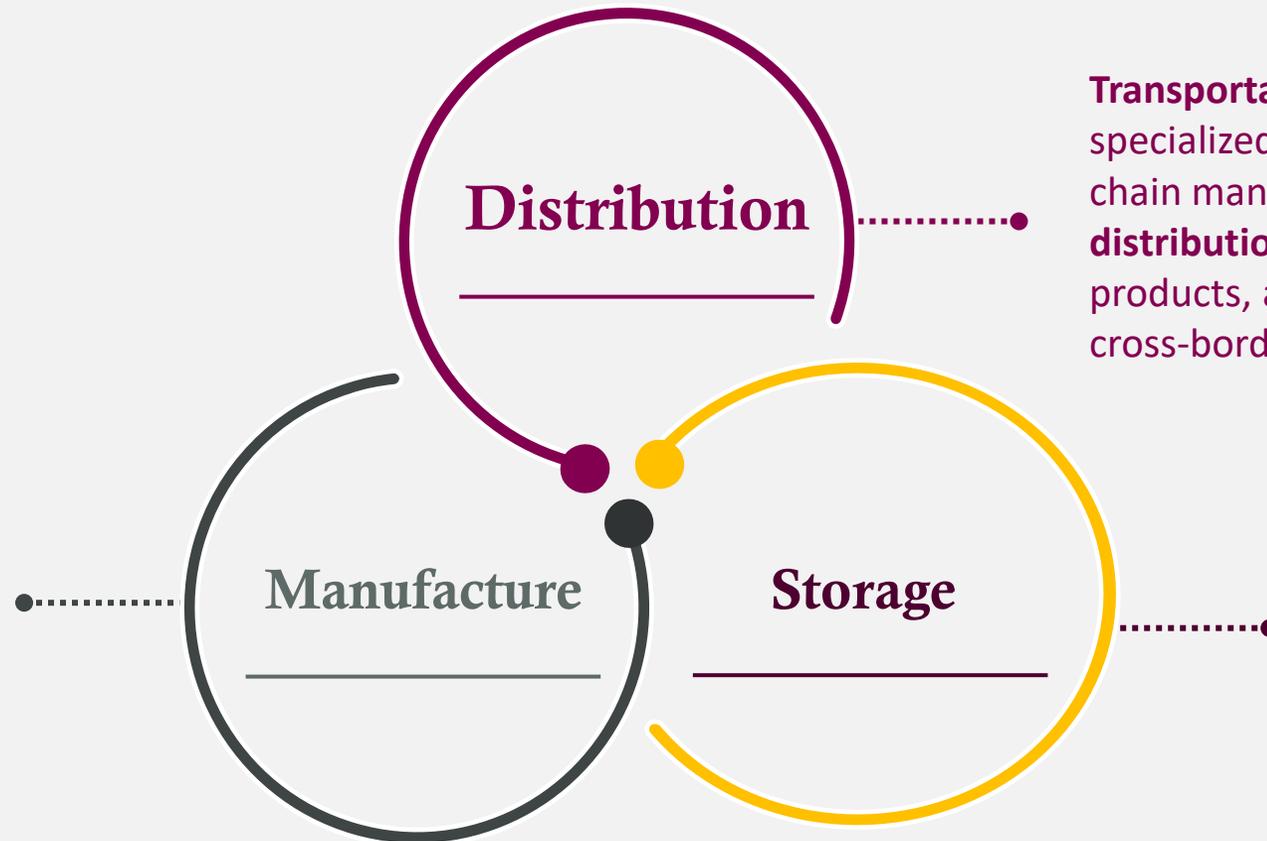
- 1** Focusing on the manufacture and delivery of biologics and cold-sensitive investigational medicinal products to clinical sites.
- 2** Outline key criteria for selecting partners to ensure alignment with project goals.
- 3** Implementing quality assurance measures during the partner selection process.



Key Focus of Today's Presentation

We will consider three essential cost categories for our clinical trials for **Labelling, Packaging, Storage and Distribution**

Label design, printing, and **labelling**, packaging materials, operations,. These elements are crucial in ensuring the **safety, compliance, and proper identification** of IMPs throughout the trial period.



Transportation, import/export **duties**, specialized handling requirements, supply chain management, **cold chain distribution** for temperature-sensitive products, and **regulatory compliance** for cross-border transportation

Temperature-controlled and Humidity-controlled environments and monitoring, security measures, inventory management, **returns & destruction**. These elements are crucial in ensuring **the integrity and stability of IMPs** throughout the trial period.



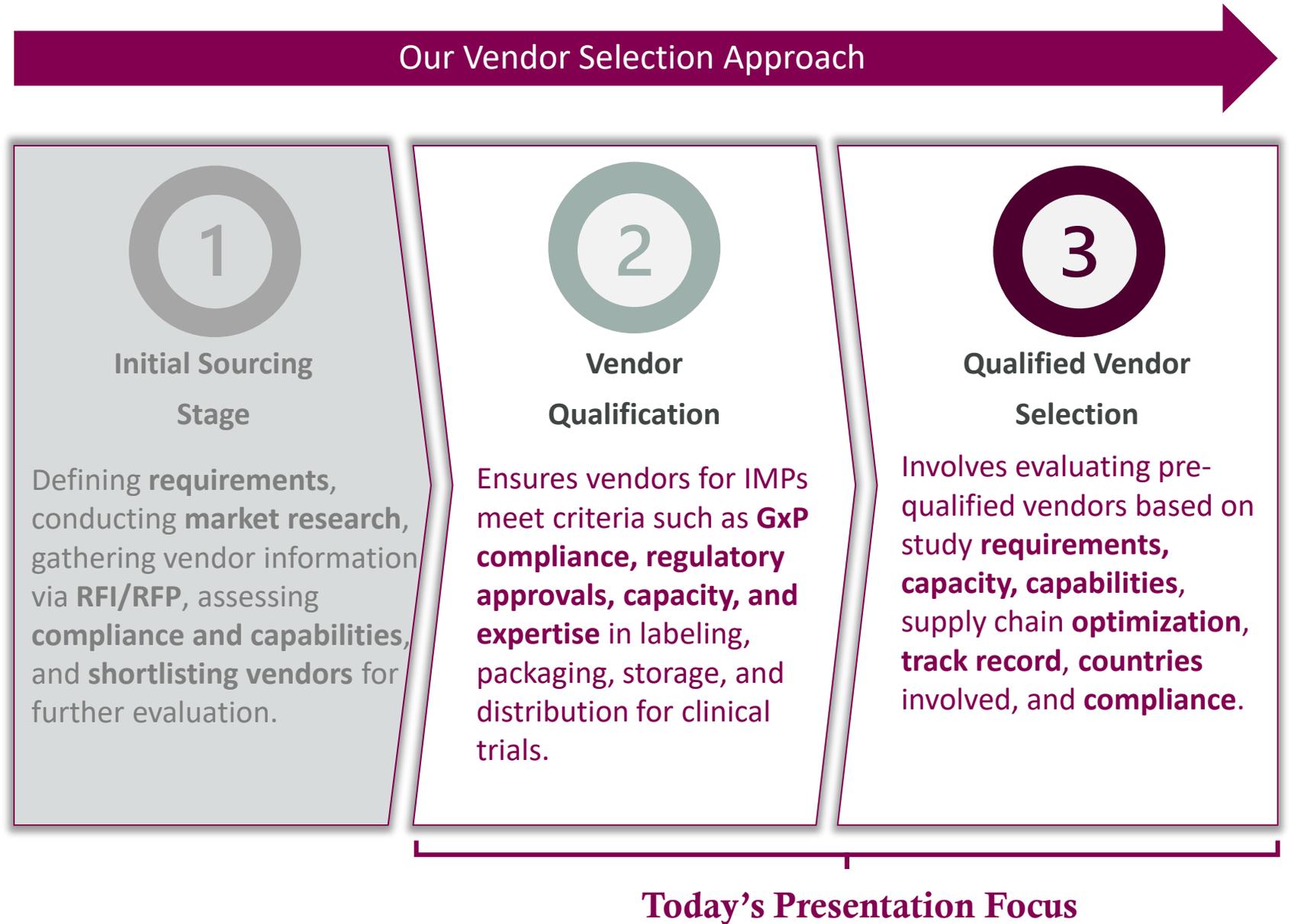
High Level Process



***Qualified Vendor:** They have established agreements (**MSA, QAA**), undergone **audits**, and are fully **prepared to operate**.

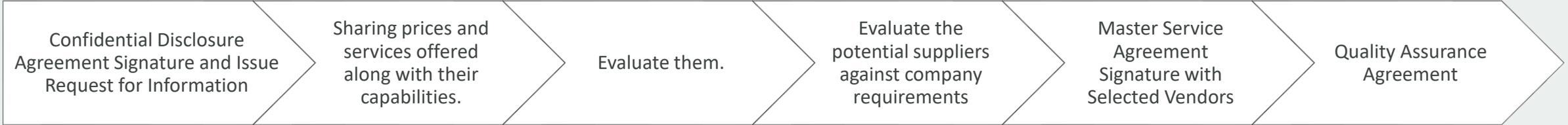


High Level Process



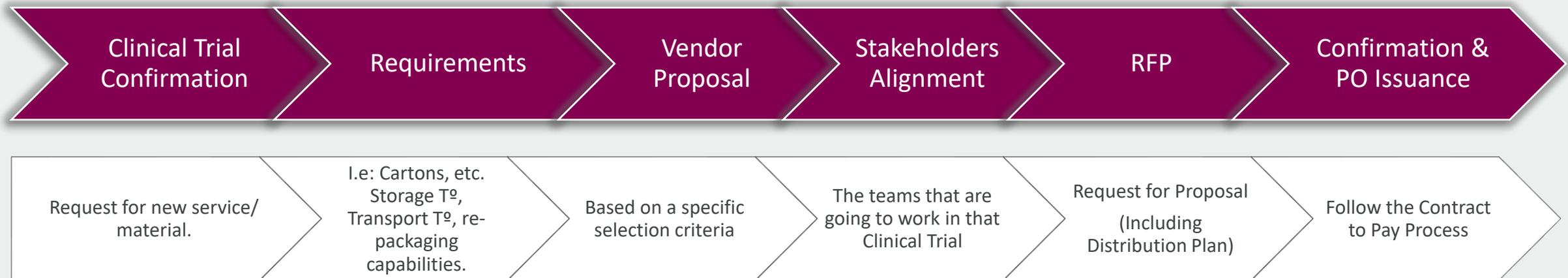
Qualified Vendor Selection for a Clinical Trial

What are the Main Steps in the Process?



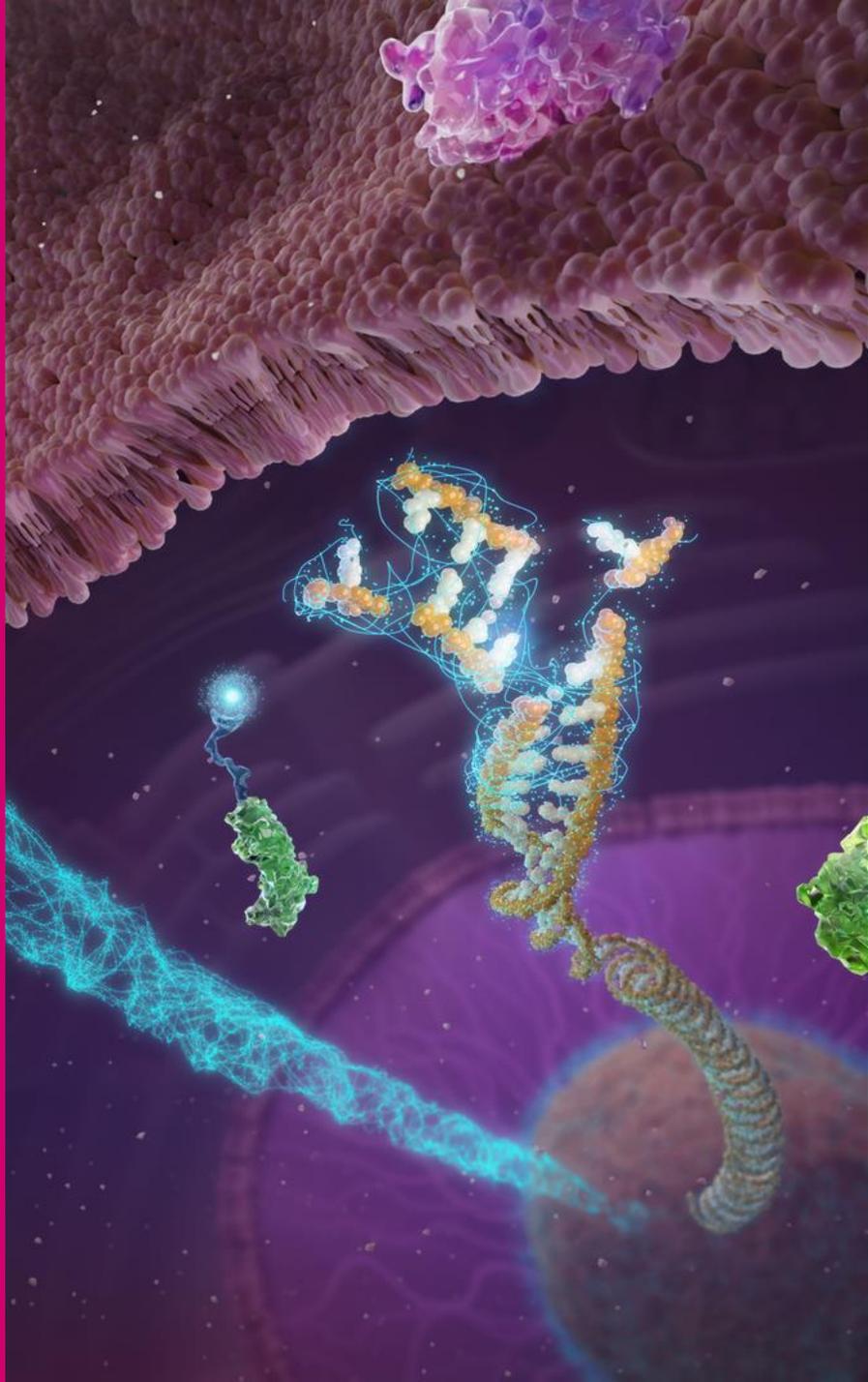
Qualified Vendor Selection for a Clinical Trial

What are the Main Steps in the Process?

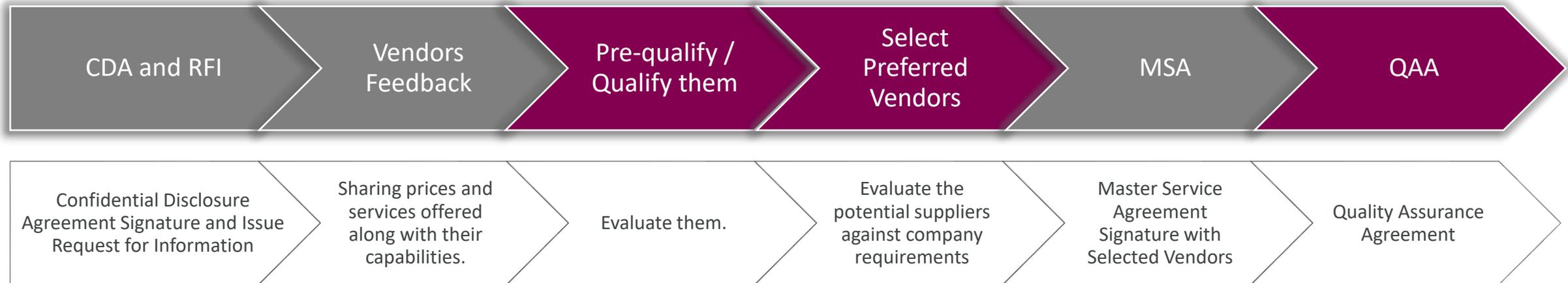


2

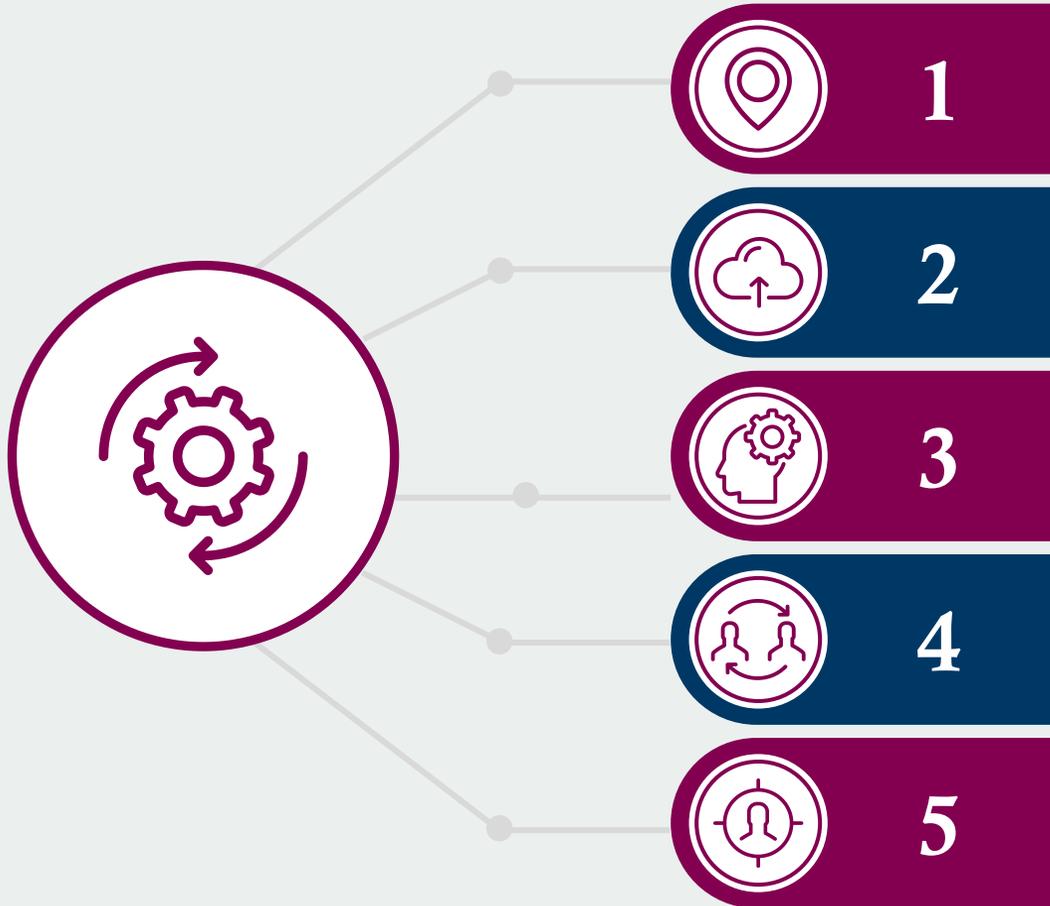
Vendor Qualification



Vendor Qualification



Vendor Qualification Considerations



1 Does the vendor comply with legal regulatory requirements?

2 What **certifications** does the vendor hold? Are there country-specific certifications required?

3 How robust is the vendor's **quality management system**?

4 What is the **vendor's audit history**? Have there been any recent quality issues?

5 How does the vendor **manage risks** related to supply chain disruptions or quality defects?



Main Quality Activities in Vendor Selection



Documentation Request

Certifications and details about facilities and services, are collected from potential vendors. A pre-qualification **questionnaire** is used, and the vendor's **quality manual** is requested to ensure alignment with defined requirements.



Quality Assurance Agreement

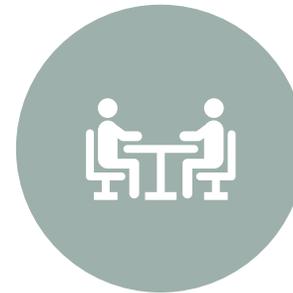
The **QAA** is drafted, agreed, and signed with the vendor before work begins. It defines **roles and responsibilities**, ensuring clarity and accountability for both parties.



Audit

Audits are conducted with a **risk-based approach**, determining the duration and number of auditors on the **vendor's criticality**.

Audit report must be properly documented and **CAPA plan** agreed with the vendor.



Continuous Monitoring

Periodic **re-evaluations** are carried out, during which **KPIs are monitored** to assess vendor performance. The outcomes influence the frequency of audits to ensure **sustained compliance** and quality standards.





Maintaining Vendor Relationships

1

KPI Monitoring and Re-Qualification

2

Periodic Audits

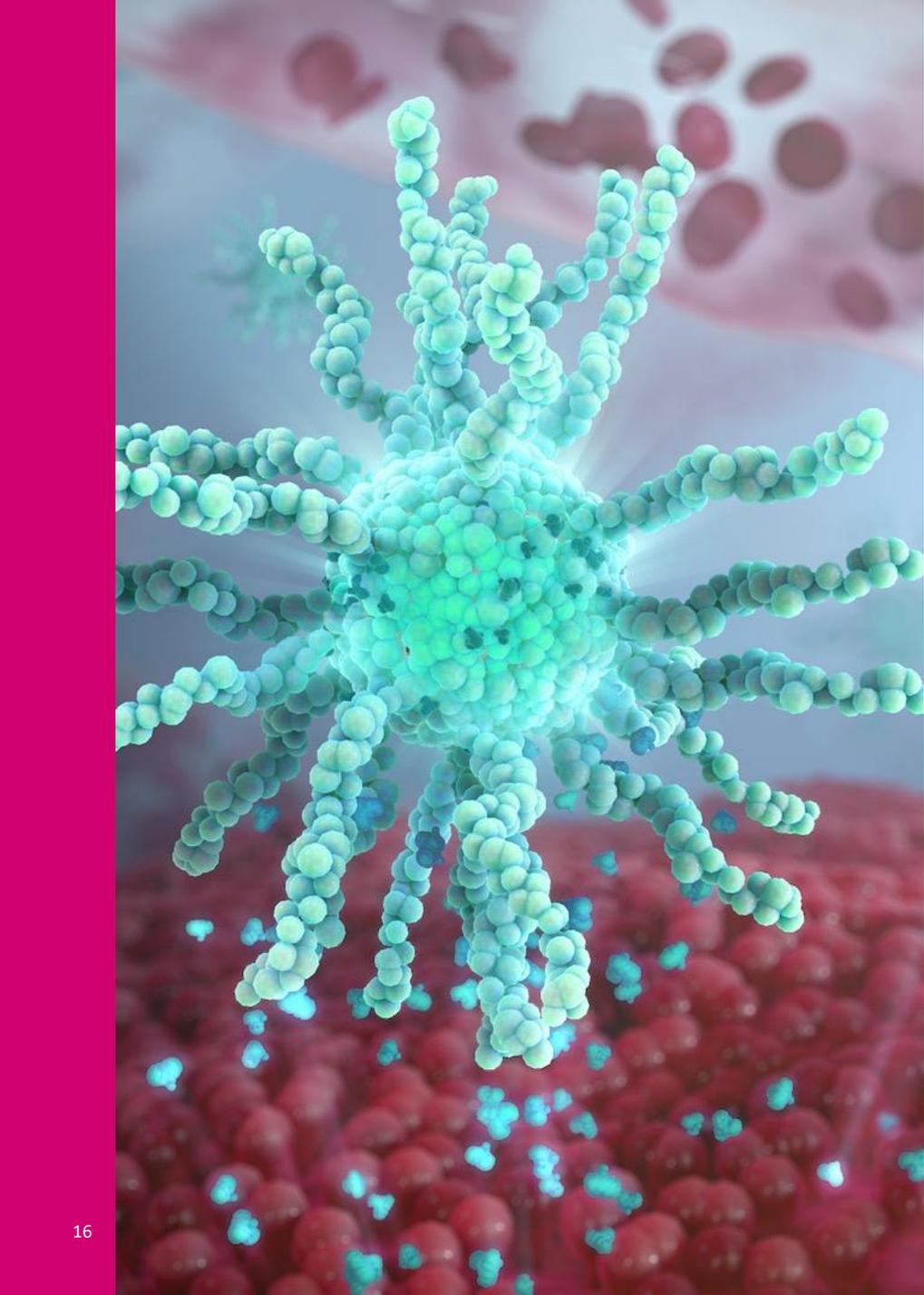
3

Supplier Management Lifecycle

4

Deviation Management and Quality Issues





3

Qualified Vendor Selection

Qualified Vendor Selection for Trial

1 Defining a Qualified Vendor

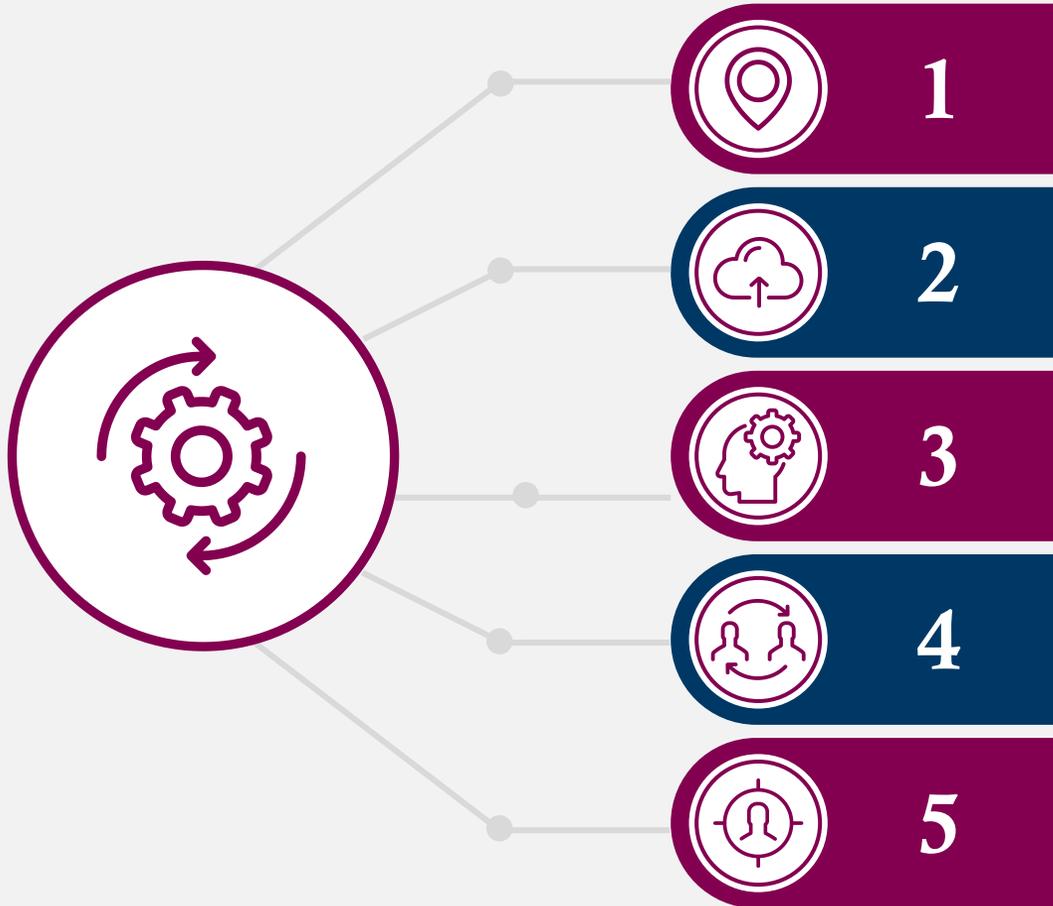
Qualified Vendors are our preferred suppliers who have completed the initial selection steps and are ready for engagement.

They have **established agreements (MSA, QAA)**, undergone **audits**, and are **fully prepared to operate**.

2 Scope of this section



Key Questions for Selecting the Right Qualified Vendor



What are the **scope of services required** for delivering IMP for the clinical trial?

Do they have the **capacity and capability** to meet our needs?

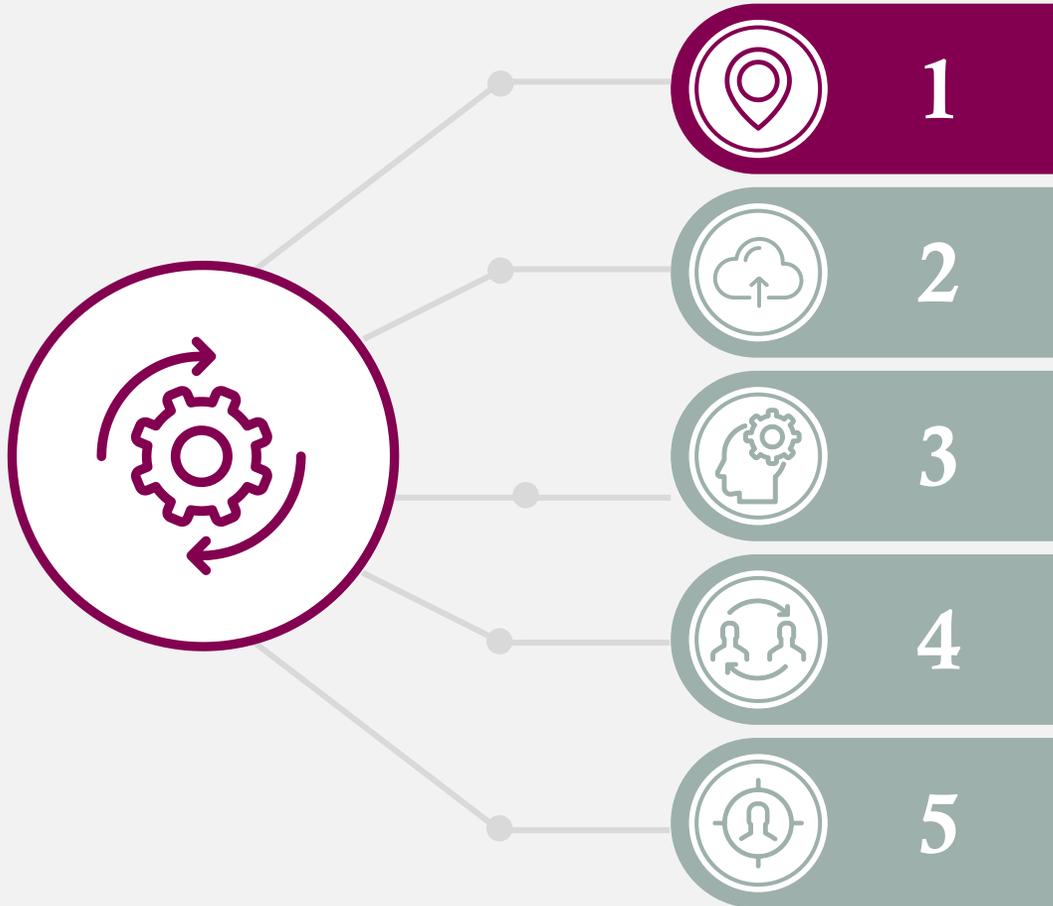
What strategy will **optimize** the supply chain and **minimize risks**?

What is their track record for **reliability and performance**?

How can we achieve **seamless international operations**?



Key Questions for Selecting the Right Qualified Vendor



What are the **scope of services required** for delivering IMP for the clinical trial?

Do they have the **capacity and capability** to meet our needs?

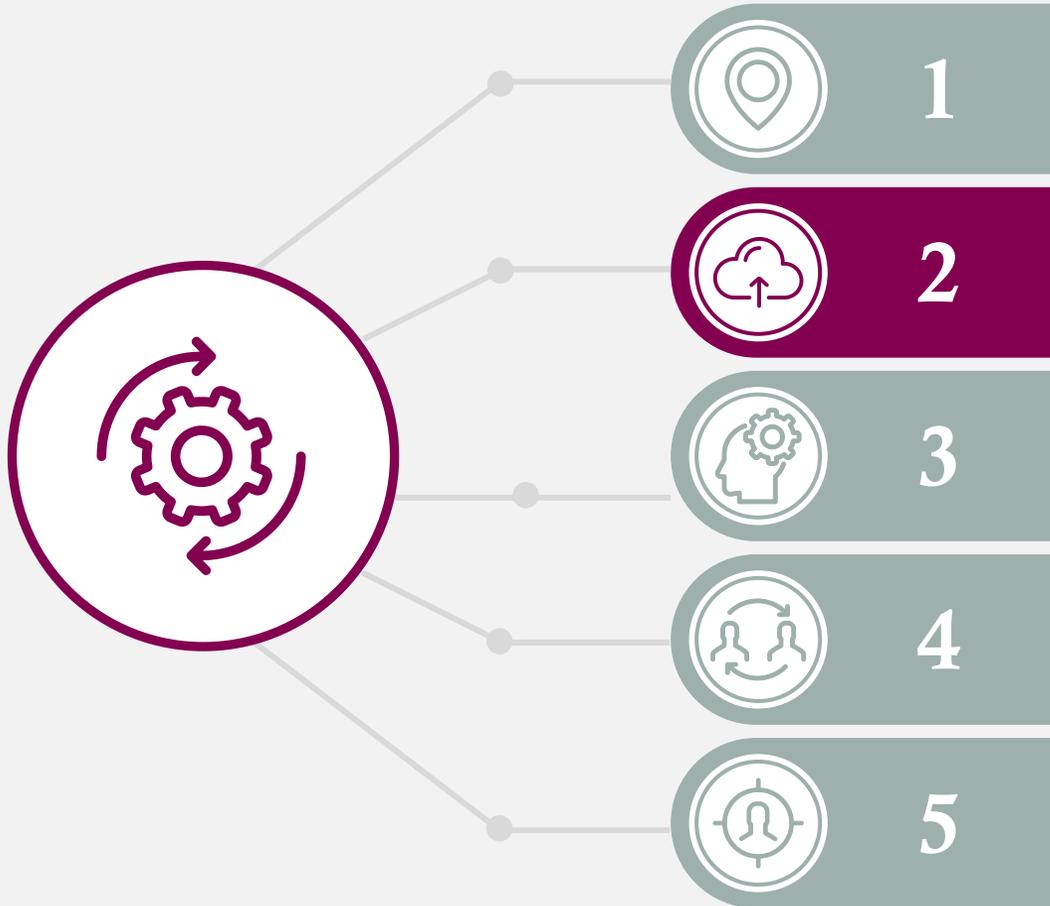
What strategy will **optimize** the supply chain and **minimize risks**?

What is their track record for **reliability and performance**?

How can we achieve **seamless international operations**?



Key Questions for Selecting the Right Qualified Vendor



1 What are the **scope of services required** for delivering IMP for the clinical trial?

2 Do they have the **capacity and capability** to meet our needs?

3 What strategy will **optimize** the supply chain and **minimize risks**?

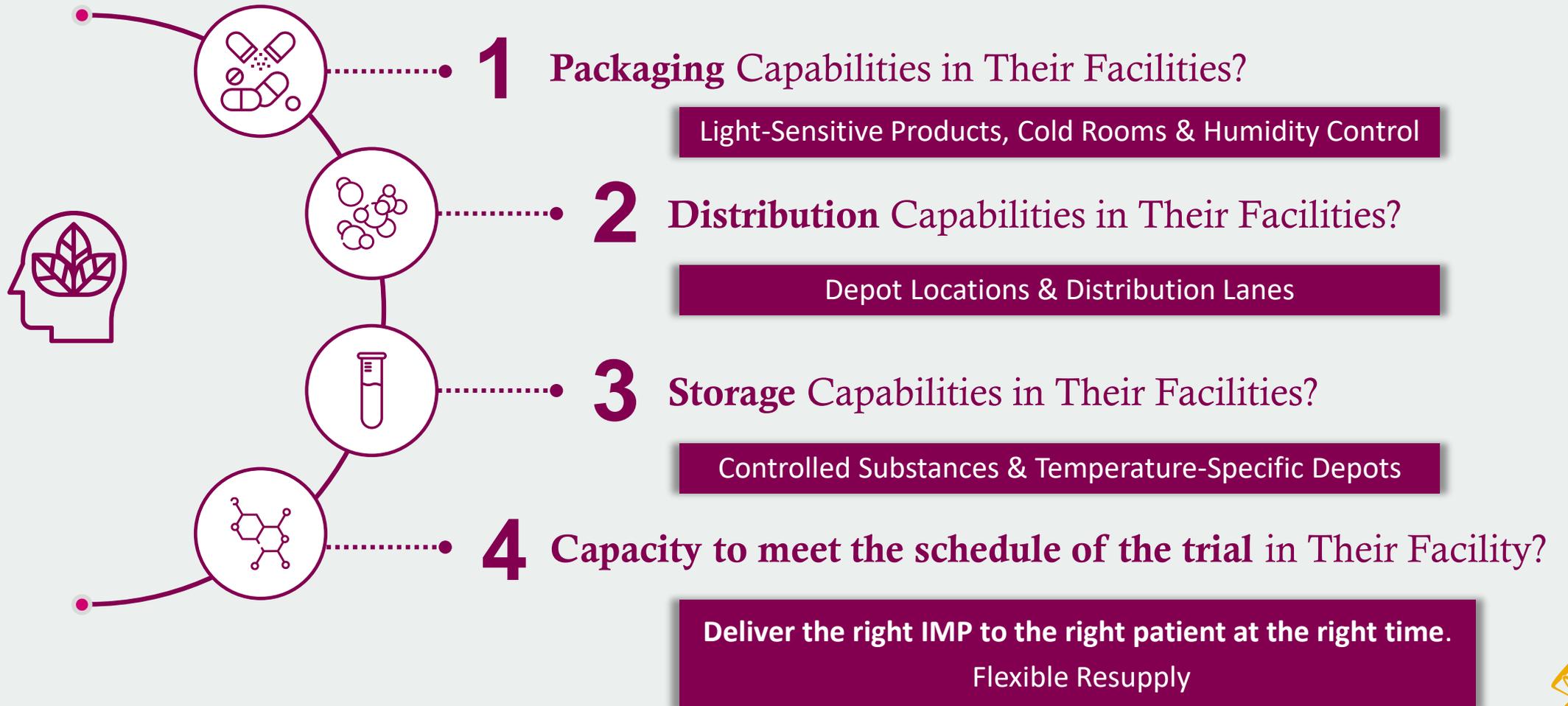
4 What is their track record for **reliability and performance**?

5 How can we achieve **seamless international operations**?

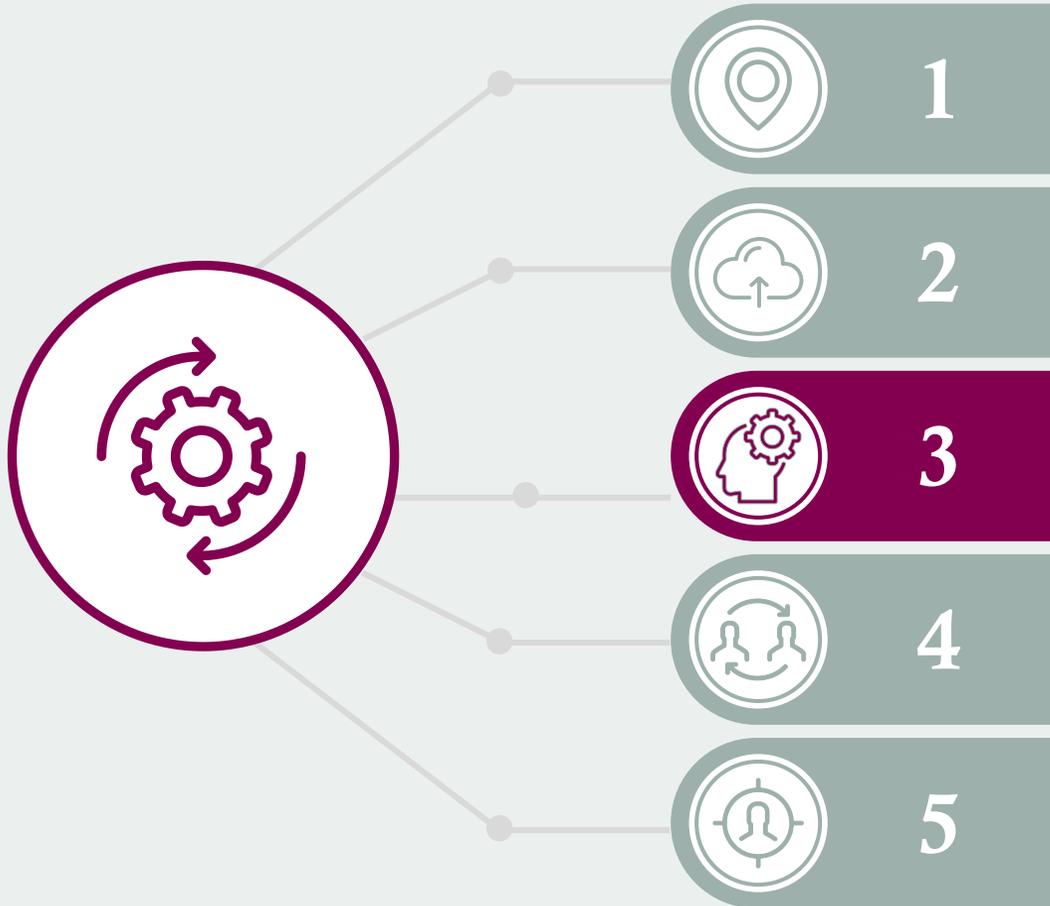


Capacity and Capabilities of the Vendor

Which Vendor(s) Meets the Required Specifications?



Key Questions for Selecting the Right Qualified Vendor



What are the **scope of services required** for delivering IMP for the clinical trial?

Do they have the **capacity and capability** to meet our needs?

What strategy will **optimize** the supply chain and **minimize risks**?

What is their track record for **reliability and performance**?

How can we achieve **seamless international operations**?

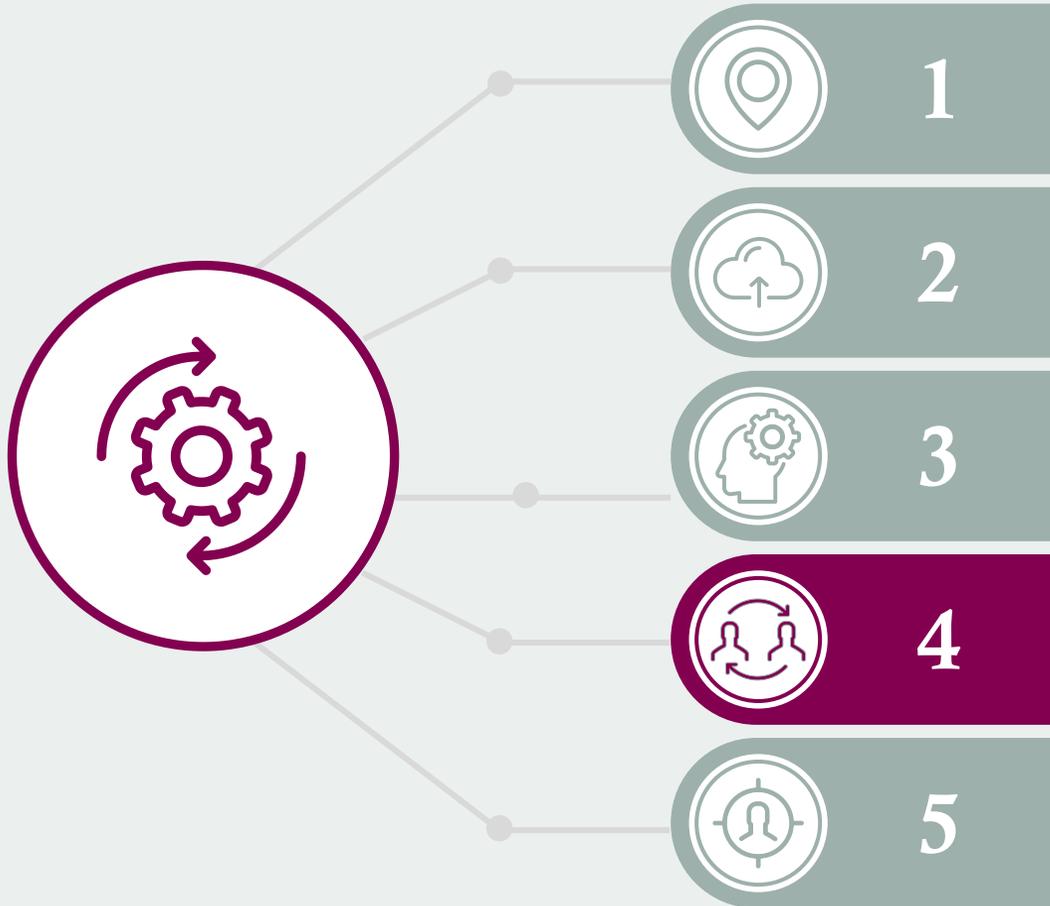


Optimize the Supply chain minimizing the risks

Which Vendor(s) Can Reduce or Simplify the Layers of Complexity?



Key Questions for Selecting the Right Qualified Vendor



What are the **scope of services required** for delivering IMP for the clinical trial?

Do they have the **capacity and capability** to meet our needs?

What strategy will **optimize** the supply chain and **minimize risks**?

What is their track record for **reliability and performance**?

How can we achieve **seamless international operations**?



Main KPIs



Jobs

27

Jobs

100%

On Time



Depot to Site Shipments

99

Shipments

97%

On Time



Transfers

33

Shipments

94%

On Time



Deviations

3

Total

100%

On Time



Days to quote

11.0

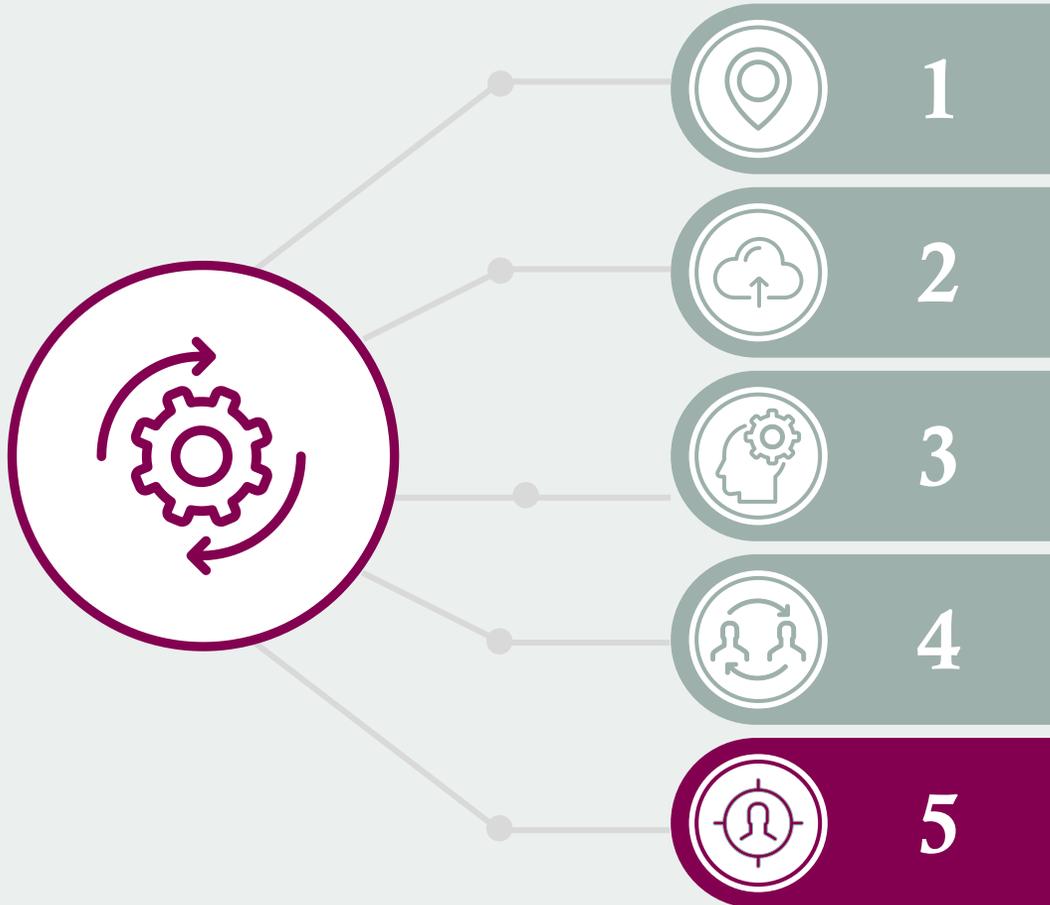
Average

70%

On Time



Key Questions for selecting the Right Qualified Vendor



What are the **scope of services required** for delivering IMP for the clinical trial?

Do they have the **capacity and capability** to meet our needs?

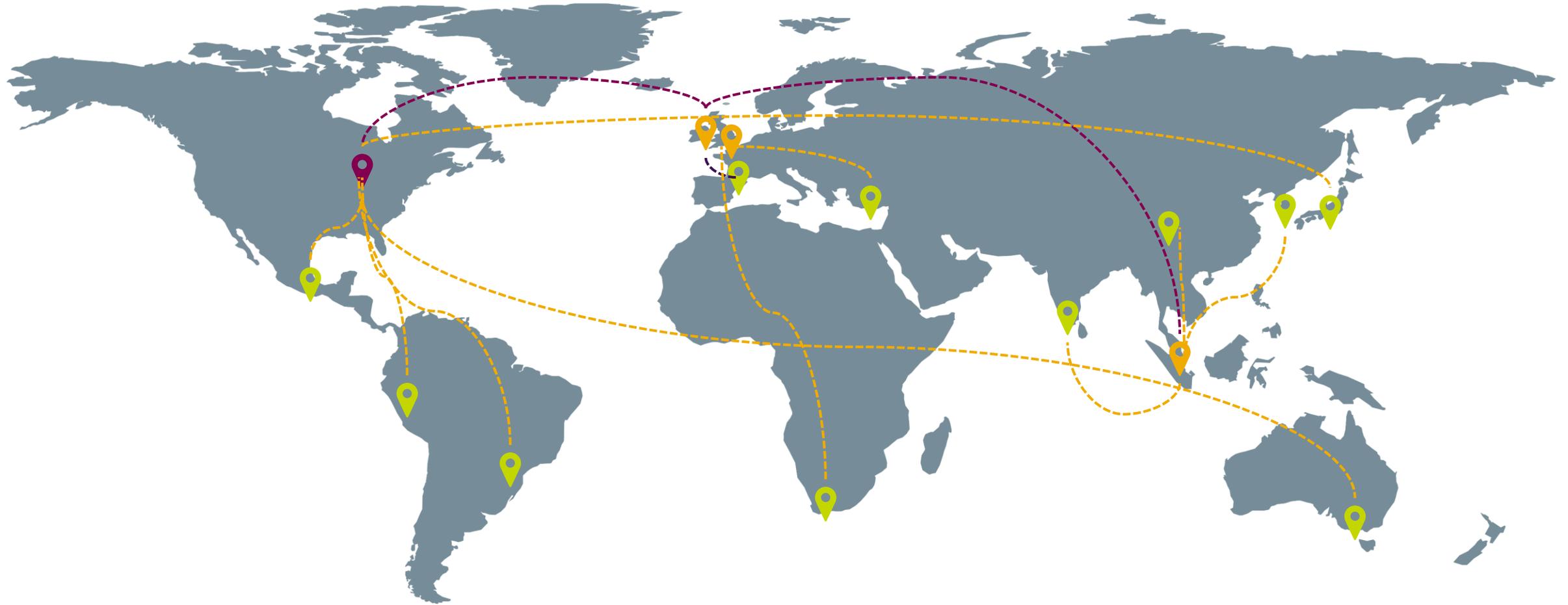
What strategy will **optimize** the supply chain and **minimize risks**?

What is their track record for **reliability and performance**?

How can we achieve **seamless international operations**?



International Partnerships and integration Large/Small vendor



- Supplier A | Drug Product
- Depot Vendor
- Sites Regions



Key takeaways



Vendor Qualification

CDA

Quality Agreement

Supplier Audit/Pre-audit

Master Service Agreement

Purchase Order



Partnership with Quality Assurance

Documentation requests

Continuous monitoring



Selection of Qualified Vendor for Clinical Trial

Proximity to Drug Product Site.

Proximity to Clinical Sites.

Appropriate Depot Network

Distribution Reliability

Deliver the right IMP to the right patient at the right time



Q&A



Confidentiality Notice

This file is private and may contain confidential and proprietary information. If you have received this file in error, please notify us and remove it from your system and note that you must not copy, distribute or take any action in reliance on it. Any unauthorized use or disclosure of the contents of this file is not permitted and may be unlawful.

AstraZeneca PLC, 1 Francis Crick Avenue, Cambridge Biomedical Campus, Cambridge, CB2 0AA, UK
+44(0)203 749 5000
www.astrazeneca.com

