

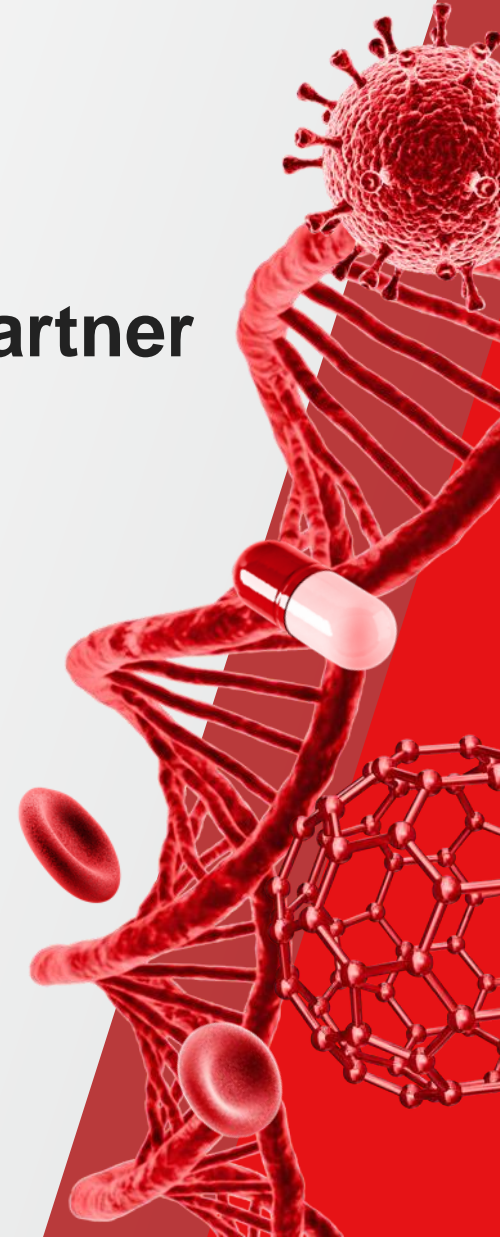
Driving success in clinical trials by choosing the right partner for your comparator sourcing global needs

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Shanghai - November 14, 2023

Beijing - November 16, 2023

 The world leader in serving science



Agenda

- 1 Market and process
- 2 Comparator sourcing capabilities
- 3 Driving success in comparator sourcing
- 4 Summary and conclusion



It is all about strategy!



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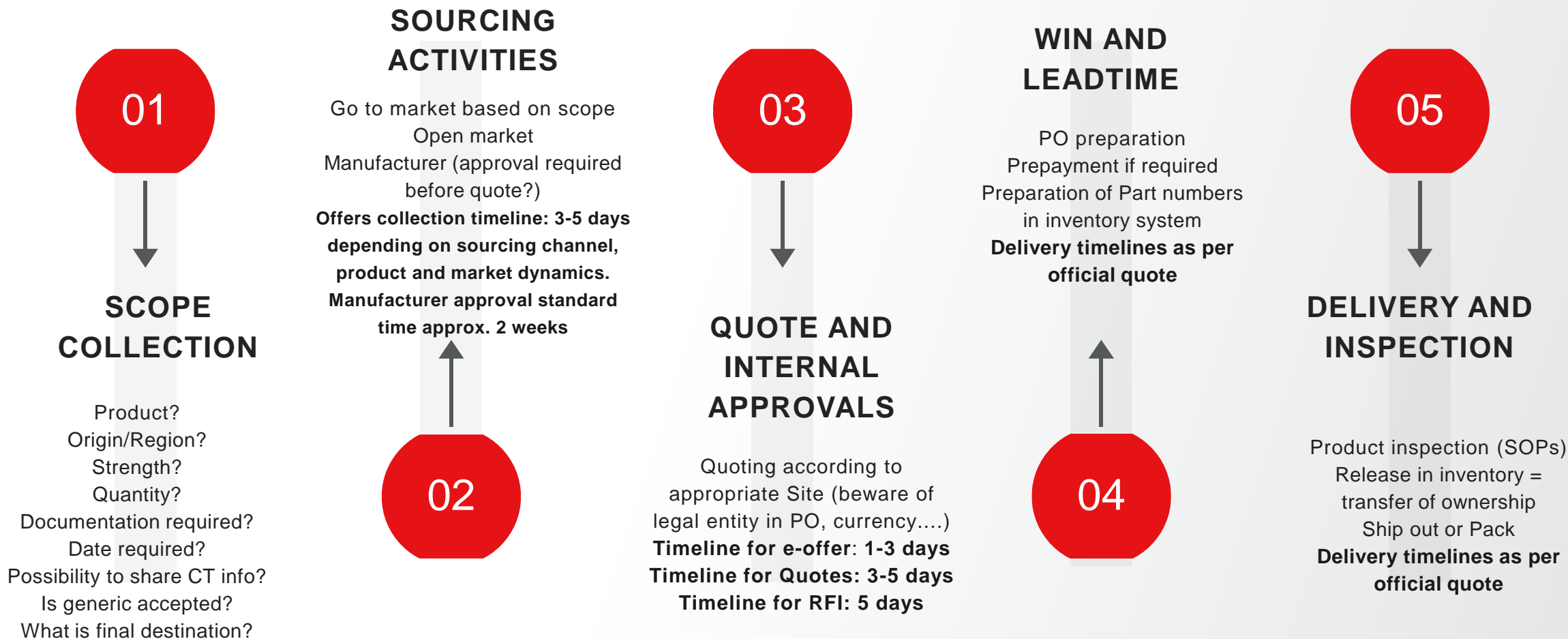
Market for comparator sourcing

Sourcing of comparators is one of biggest concern for any clinical trial sponsor considering the time sensitivity of clinical trials and cost of sourcing

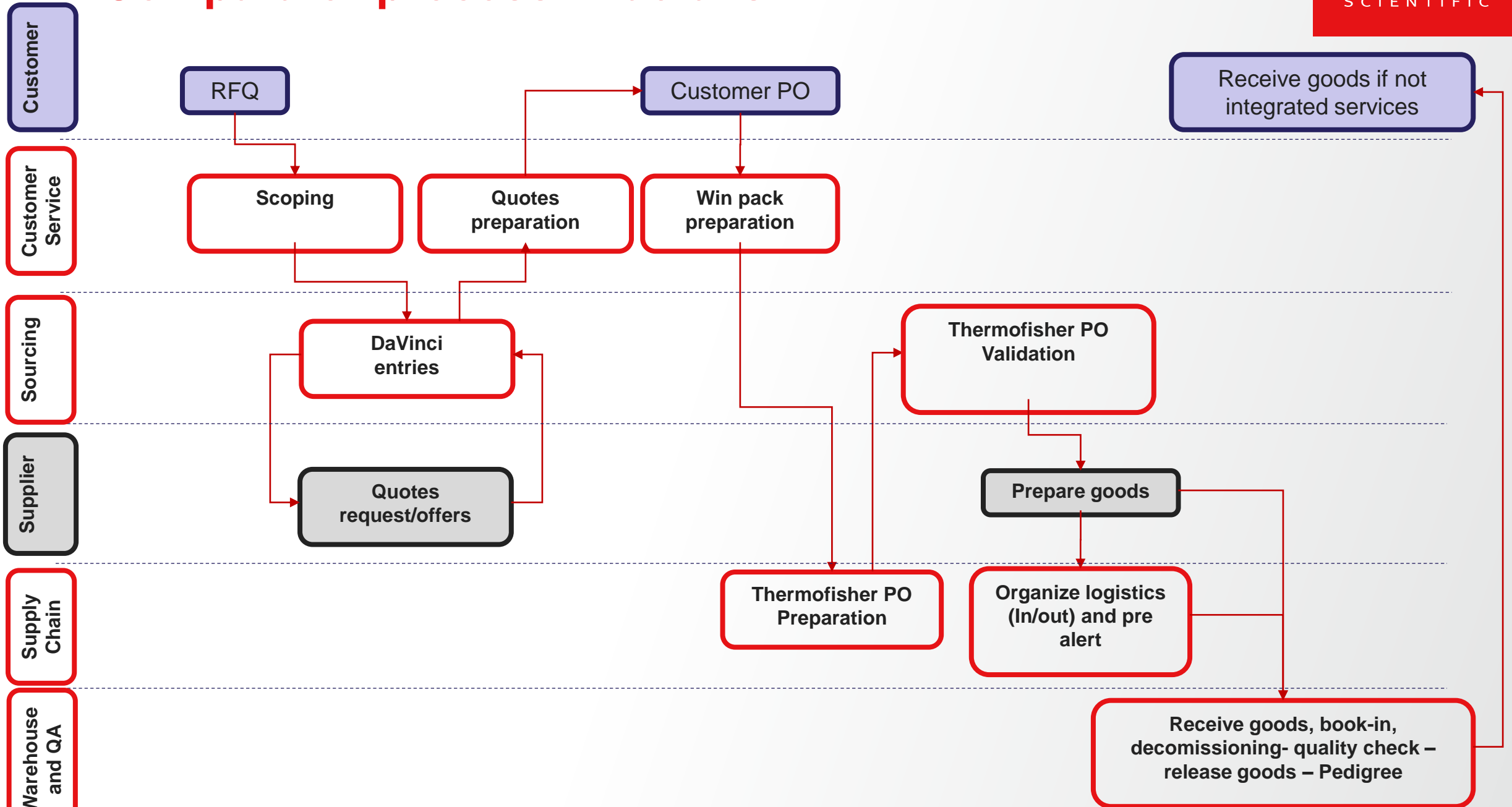
- Market size approximately of \$3B
- Comparator studies driven by intense market competition
- Shift from small molecules to biologics
- Price increase driven by expensive treatments in oncology
- Regulatory pressure and changing regulations
- Confirmed growth in emerging countries
- Move towards virtual and decentralized trials
- Increased supply chain constraints and sourcing complexity

Comparator process from project intake to distribution

Consultatory services ensure you obtain comparator needed for your trial to proceed as planned



Comparator process in details



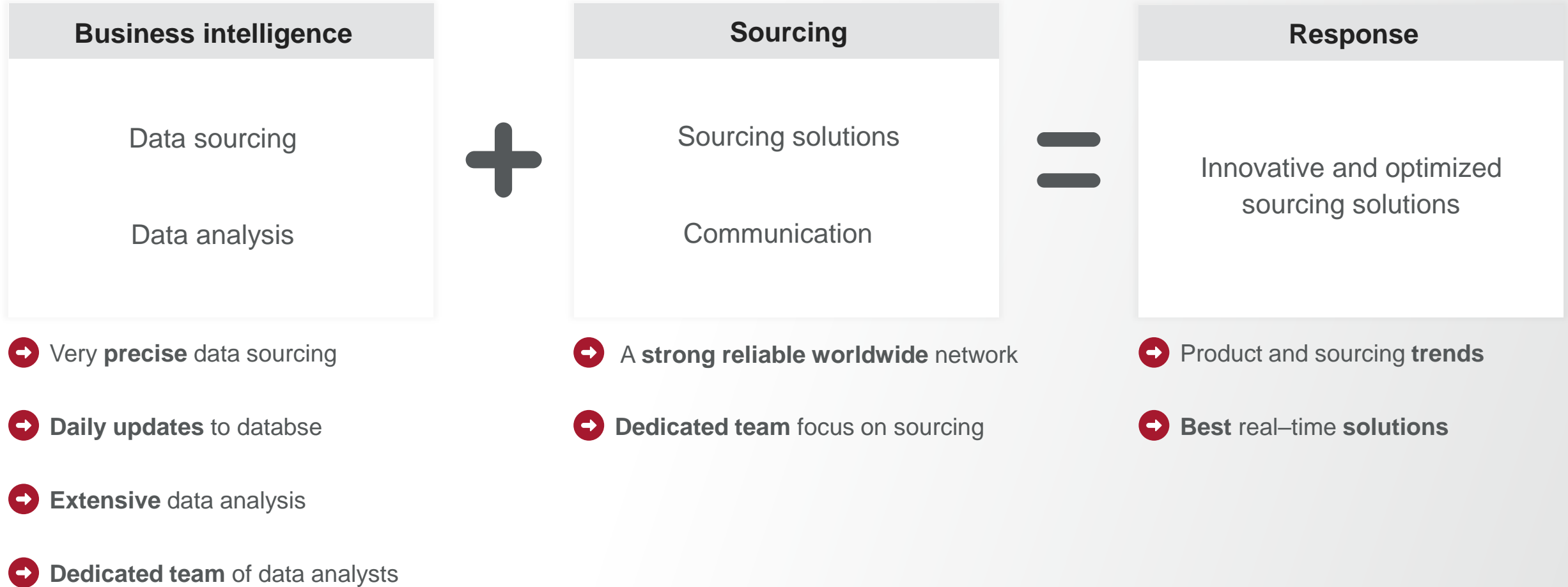
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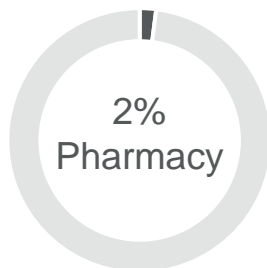
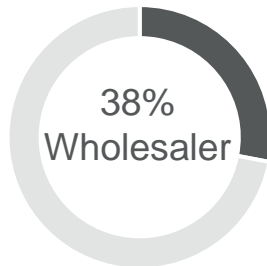
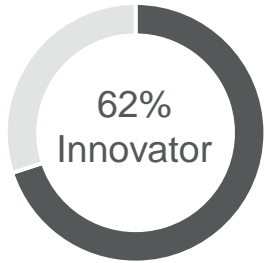
Market intelligence

A collaboration at your service



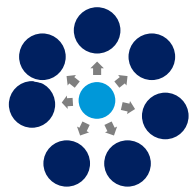
Sourcing network of hundreds of global sourcing options

A global network with unparalleled access to information enables reliable and cost-efficient sourcing



Sourcing options depend on trial design

Different sourcing options will help you to design your strategy based on your trial specifics



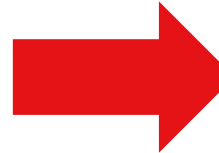
Central sourcing

Sourcing one make-up in one single country for all countries involved in the trial



Direct sourcing

Sourcing from the MA holder



Local sourcing

Sourcing a commercially available product in each country, for use in the same country



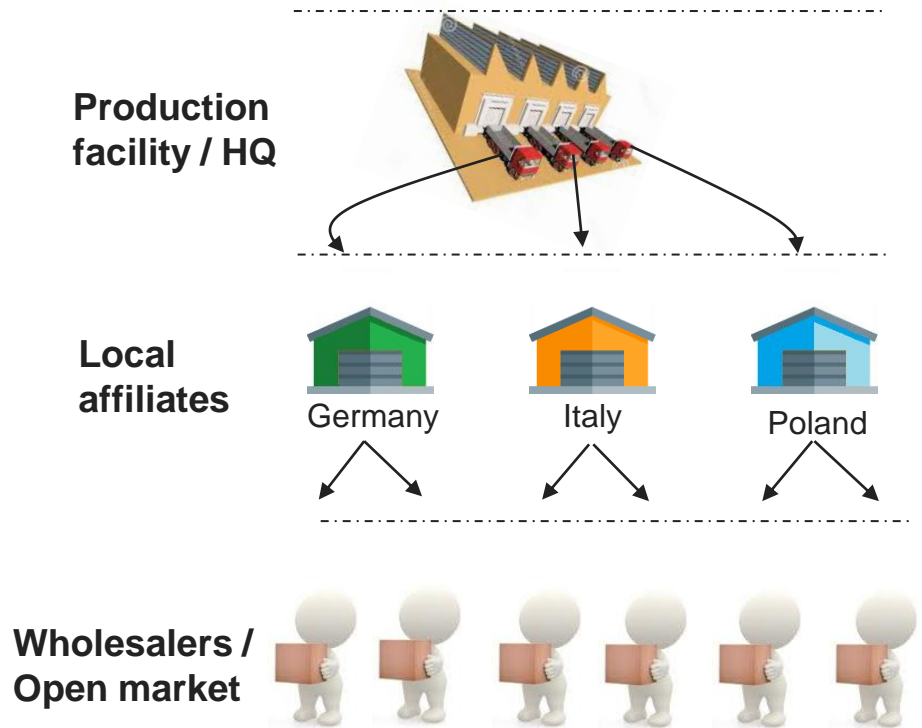
Open Market sourcing

Sourcing from the Wholesalers or Pharmacies



Example of EU Market and it specificities

Define your supply chain specifics to target the right source

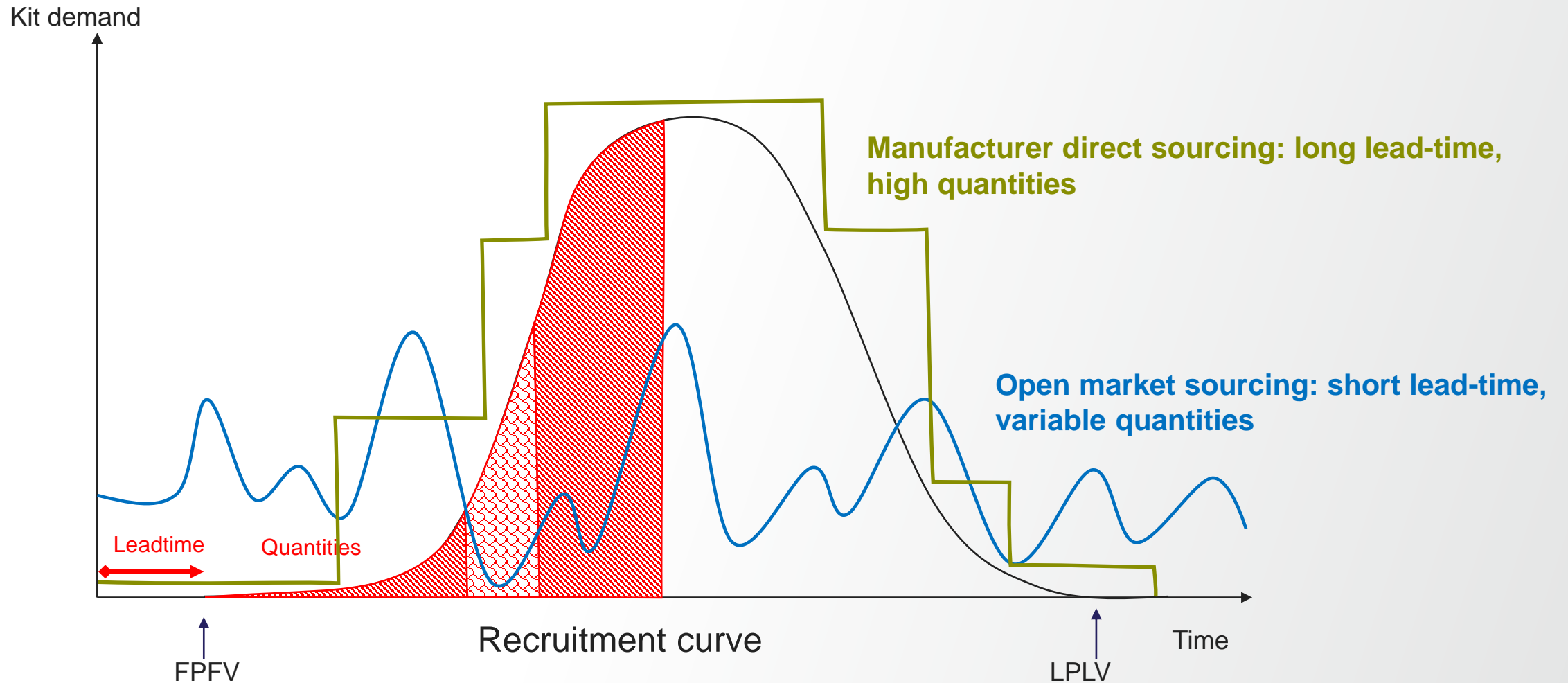


Unit price	Lead-time	Documentation	Quantities	Continuity	Fit for use	Label language	Samples	Shelf life	Inbound
-	-	+	+	++	++	+	-	++	++
+/-	+/-	+/-	+/-	+/-	+	-	-	+	+
+/--	+	-	+/--	-	-	-	+	+/-	-

+ is positive category - is negative category

Example of hybrid sourcing in strategy definition

Early involvement of Comparator Expert and providing forecast has a big impact on setting up strong and optimal strategy and supply chain



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Need to adapt from a tactical to a strategic approach

2010 90% Small molecule

- Less challenge in production
- Low cost
- Low complexity
- Shorter leadtime
- Ambient



2030 90% Biologic

- Challenging production
- Higher cost
- Higher complexity
- Longer leadtime
- Cold Chain



Balancing unit costs and value

Selecting the right source is more valuable than price negotiation

- What is the best market? *Product dependence*
- Is the cheapest always best? *Reliability/KPIs*
- What about price increase predictability? *WAC frequency*
- How can I maintain price over years? *Supply agreements*
- What is current Market behavior? *ie shortage*
- Is the supplier giving other advantages? *ie Bulk*
- Negotiation with Manufacturers? *Who needs who?*



Trial budget

Leveraging agility and speed

Proactivity is efficient, reactivity is a must

- What is behind -time? *Steps of sourcing*
- Can you rush a Manufacturer? *Commercial priority*
- First come First served? *Do not miss the stock or ...*
- What are best sources regarding lead time? *Downstream*
- What about backup plan? *Example*



Lead-time

Ensuring robust supply chain

Never forget that a patient is waiting

- What is the strongest supply chain? *Supply agreements*
- Which source fits my trial demand? *Stock vs Demand*
- Can I mix sources? *If yes, should I?*
- Drawback of strong supply chain? *Am I flexible?*



Supply Chain Strength

Getting documentation can be a challenge

Do you really need it?



Documentation

- Why is it difficult to obtain? *Not used in commercial*
- Where is it difficult to obtain? *Downstream*
- Can I make savings with documentation? *Equivalency*
- Why do I ask documentation? *Example (RUS)*

Execution is key

Ensuring logistics in and out will mitigate risks

- Product transfer: Do I consider VAT? *Where do I source, where does it go?*
- Do I have all paperwork? *Import License requirement per country*
- Do I have strong Partner for logistics? *Cold Chain*
- What if there is a temperature excursion? *Temperature Excursions?*



Goods movement

Quality is not negotiable

Work with a compliant supplier to be compliant yourself



- Monitoring of regulatory framework and compliance
- Securing the supply chain and avoiding counterfeits
- Harmonizing procedures and quality system through 20 owned facilities
- Auditing and qualifying all suppliers in 45+ countries
- Managing temperature-controlled chain including handling of temperature excursions
- Inspecting visually 100% all deliveries from wholesalers

Comparator value stream

Through value stream we mitigate risks and assure end-to-end supply chain for trial sponsors



Market insights
Visibility
Transparency

Continuity of supply
Demand planning
Fixed pricing

Enhance
Efficiency
Waste management

Global alignment
Efficient
Communication

Information flow
Flawless
Execution
Full service integration

QA integration
Roadblocks
Challenges

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Five golden rules to drive successful comparator sourcing

Ensuring a stable and risk-free supply of comparator medications

- ✓ Take a strategic sourcing approach and involve early your Comparator Sourcing Specialist
- ✓ Ensure proper end-to-end scoping of your project for best strategy definition
- ✓ Consider all viable sourcing options and don't focus solely on costs
- ✓ Leverage forecast from early stage and adapt demand planning
- ✓ Have a plan in case of supply disruption and unexpected events

The patient is at the center of everything we do



- ✓ Thermo Fisher has a proven track record of creating value for sponsors
- ✓ For 30+ years, Thermo Fisher experts have delivered best in class clinical supply services to empower customer pipelines
- ✓ Extensive network redundancy will serve to mitigate risk and meet evolving regulatory requirements
- ✓ Thermo Fisher's continuous improvement culture drives operational efficiency and high-quality standards

谢谢
Thank You

Q&A

