

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

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- 1 Market and process
- 2 Comparator sourcing capabilities
- 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 oncololgy
- 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



Product?
Origin/Region?
Strength?
Quantity?
Documentation required?
Date required?
Possibility to share CT info?
Is generic accepted?
What is final destination?

SOURCING ACTIVITIES

Go to market based on scope Open market Manufacturer (approval required before quote?)

Offers collection timeline: 3-5 days depending on sourcing channel, product and market dynamics.

Manufacturer approval standard time approx. 2 weeks





QUOTE AND INTERNAL APPROVALS

Quoting according to appropriate Site (beware of legal entity in PO, currency....) Timeline for e-offer: 1-3 days Timeline for Quotes: 3-5 days Timeline for RFI: 5 days

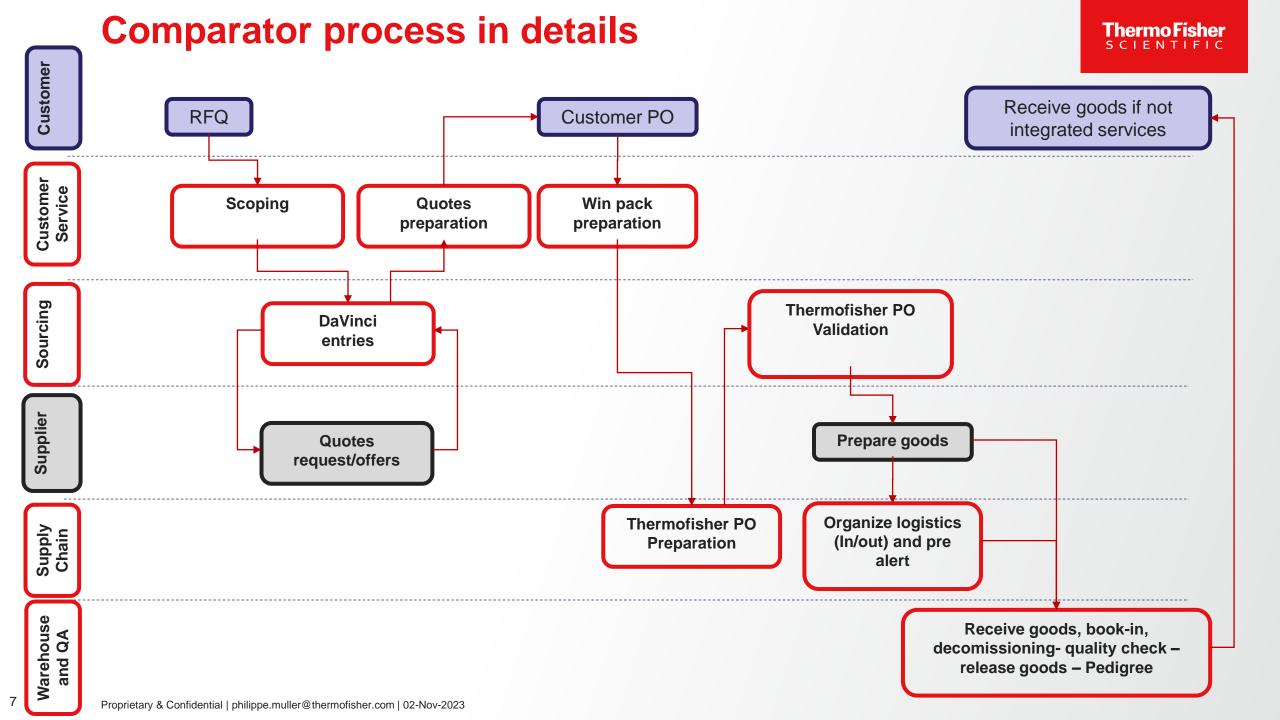
WIN AND LEADTIME

PO preparation
Prepayment if required
Preparation of Part numbers
in inventory system
Delivery timelines as per
official quote





Product inspection (SOPs)
Release in inventory =
transfer of ownership
Ship out or Pack
Delivery timelines as per
official quote



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Market intelligence



A collaboration at your service

Business intelligence

Data sourcing

Data analysis

- Very **precise** data sourcing
- **Daily updates** to databse
- **Extensive** data analysis
- Dedicated team of data analysts

Sourcing

Sourcing solutions

Communication

- A strong reliable worldwide network
- Dedicated team focus on sourcing

Response

Innovative and optimized sourcing solutions

- Product and sourcing **trends**
- Best real-time solutions



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



- Product specification
- Quantities
- Countries involved
- Timelines
- Need for documentations
- Study complexity
- CT data availability



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

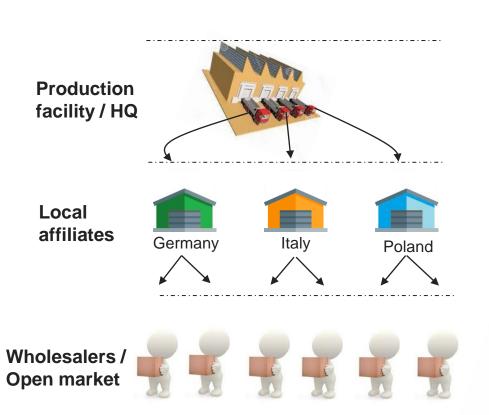


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Example of EU Market and it specifities

Define your supply chain specifics to target the right source



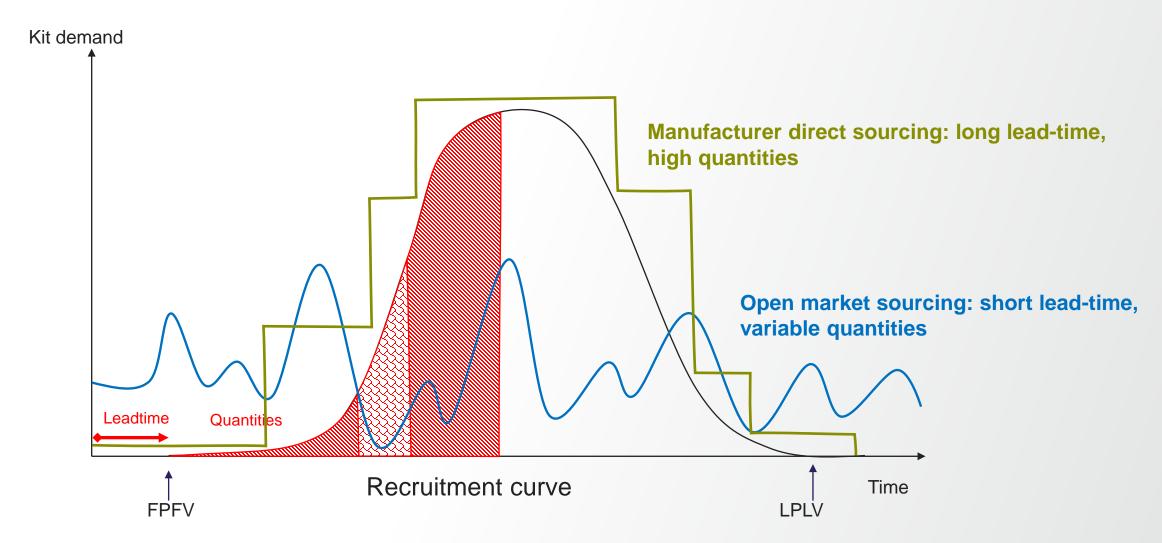
Unit price	Lead-time	Documentation	Quantities	Continuity	Fit for use	Label language	Samples	Shelf life	Inbound
-	-	+	+	++	++	+	-	++	++
+/-	+/-	+/-	+/-	+/-	+	-	-	+	+
+/	+	-	+/	-	-	-	+	+/-	-

+ 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



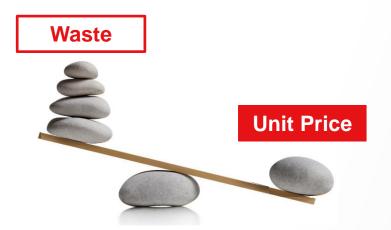
2010 90% Small molecule

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



2030 90% Biologic

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



Savings driven by tactical negotiation



Savings driven by strategy definition

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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 !?
- 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

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Ensuring logistics in and out will mitigate risks



Goods movement

- > 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?*

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 intelligence

Supply agreements

Flexible sourcing

Stakeholder management

Monitoring

Risk mitigation

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

